DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

[Docket No. FSIS-2022-0013]

Salmonella in Not-Ready-To-Eat Breaded Stuffed Chicken Products

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Proposed Determination and Request for Comments.

SUMMARY: The Food Safety and Inspection Service (FSIS) is proposing to declare that not- ready-to-eat (NRTE) breaded stuffed chicken products that contain *Salmonella* at levels of 1 colony forming unit (CFU) per gram or higher are adulterated within the meaning of the Poultry Products Inspection Act (PPIA). Although the labeling of these products has undergone significant changes over time to better inform consumers that they are raw and to provide instructions on how to prepare them safely, NRTE breaded stuffed chicken products continue to be associated with *Salmonella* illness outbreaks. Therefore, FSIS has concluded that public health measures that focus primarily on product labeling and consumer handling practices have not been effective in preventing additional foodborne illnesses associated with NRTE breaded stuffed chicken products. FSIS is also proposing to carry out verification procedures, including sampling and testing of the chicken component of these products prior to stuffing and breading, to ensure producing establishments control *Salmonella* in these products.

DATES: Comments on this proposed determination and the proposed verification procedures must be received on or before **[Insert date 60 days after publication in Federal Register]**. FSIS specifically requests comments on alternative bases for determining adulteration of breaded stuffed NRTE products.

ADDRESSES: FSIS invites interested persons to submit comments on this document. Comments may be submitted by one of the following methods:

• Federal eRulemaking Portal: This website provides the ability to type short comments directly into the comment field on this web page or attach a file for lengthier comments. Go to https://www.regulations.gov. Follow the on-line instructions at that site for submitting comments.

• Mail: Send to Docket Clerk, U.S. Department of Agriculture, Food Safety and Inspection Service, 1400 Independence Avenue SW, Mailstop 3758, Washington, DC 20250-3700.

• Hand- or courier-delivered submittals: Deliver to 1400 Independence Avenue SW, Jamie L. Whitten Building, Room 350-E, Washington, DC 20250-3700.

Instructions: All items submitted by mail or electronic mail must include the Agency name and docket number **FSIS-2022-0013**. Comments received in response to this docket will be made available for public inspection and posted without change, including any personal information, to https://www.regulations.gov.

Docket: For access to background documents or comments received, call (202) 937-4272 to schedule a time to visit the FSIS Docket Room at 1400 Independence Avenue SW, Washington, DC 20250-3700.

FOR FURTHER INFORMATION CONTACT: Rachel Edelstein, Assistant Administrator, Office of Policy and Program Development, FSIS, USDA; Telephone: (202) 937-4272.

SUPPLEMENTARY INFORMATION:

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I. Background

Pathogens as Adulterants in Raw and Not-Ready-To Eat Meat and Poultry Products

Under the Federal Meat Inspection Act (FMIA) (21 U.S.C. 601 *et seq*.) and the Poultry Products Inspection Act (PPIA)(21 U.S.C 453 *et seq.*), a meat or poultry product is adulterated if, among other circumstances, "it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance, such article shall not be considered adulterated … if the quantity of such substance in or on such article does not ordinarily render it injurious to health" (21 U.S.C. 601(m)(1); 21 U.S.C. 453(g)(1)). Meat and poultry products are

also adulterated if they are "unsound, unhealthful, unwholesome, or otherwise unfit for human food" (21 U.S.C. 601(m)(3)); 21 U.S.C. 453(g)(3)).

Historically, most foodborne pathogens, including *Salmonella*, have not been considered as adulterants of raw and other NRTE meat and poultry products based on the assumption that ordinary cooking is generally sufficient to destroy the pathogens.[1,2] The exceptions are *Escherichia coli* O157:H7 (*E. coli* O157:H:7)[3] and certain non-O157 Shiga toxin-producing *Escherichia coli* (STEC) in raw, non-intact beef products and intact cuts that are to be further processed into non-intact products before being distributed for consumption. As discussed below, these pathogens are considered adulterants in these specific raw products because they render "injurious to health" what many consumers believe to be properly cooked non-intact beef products. [4]

STEC as Adulterants

When FSIS determined that certain STEC are adulterants in non-intact raw beef products, the Agency identified characteristics associated with both the pathogen and the product that distinguish them from other raw products contaminated with other pathogens. Specifically, in 1994, when FSIS initially notified the public that raw ground beef products contaminated with *E. coli* O157:H7 are adulterated within the meaning of the FMIA, the Agency noted that exposure to *E. coli* O157:H7 organisms had been linked with serious, life-threatening human illnesses, such as hemorrhagic colitis and hemolytic uremic syndrome (HUS).[5] In addition, FSIS noted that only small numbers of *E. coli* O157:H7 organisms may cause illness. Because of its low infectious dose, FSIS also noted that *E. coli*

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[1] See proposed rule "Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP) Systems," February 4, 1993 (60 FR 6774 at 6798-6799) and final rule "Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP) Systems," July 25, 1996 (61 FR 38806 at 38835.) See also *Amer. Public Health Ass'n v. Butz*, 511 F.2d 331 (U.S. App. D.C., 1974).

[2] When raw meat or poultry products are associated with an illness outbreak and contain pathogens that are not considered adulterants in those products, FSIS considers the product linked to the illness outbreak to be adulterated under 21 U.S.C. 601(m)(3) or 453(g)(3) because the product is "…unsound, unhealthful, unwholesome, or otherwise unfit for human food" (77 FR 72681, 72689 (Dec. 6, 2012). Products that contain an adulterant are considered adulterated under 21 U.S.C. 601(m)(1) or 453(g)(1) even if they are not linked to an illness outbreak.

[3] On April 16, 2021, FSIS announced that it was aligning the testing criteria for *E. coli* O157:H7 with that for non-O157 STEC. Under the updated method, consistent with laboratory testing for non-O157 STEC, an *E. coli* O157:H7 isolate is confirmed positive if it has a *stx* gene, an *eae* gene, and is identified by the laboratory as O157. FSIS no longer performs H7 gene testing. FSIS began using the updated method on samples received on or after May 17, 2021. (see FSIS Announces Updates to Laboratory Testing Criteria for Escherichia coli (E. coli) O157:H7, FSIS Constituent Update (April 16, 2021). Available at: https://www.fsis.usda.gov/news-events/news-press-releases/constituent-update-april-16-2021)

[4] See *Texas Food Industry Association v. Espy*, 870 F. Supp. 143 (1994).

[5] Michael R. Taylor, FSIS Administrator. September 29, 1994. ''Change and Opportunity to Improve the Safety of the Food Supply." Speech to American Meat Institute Annual Convention, San Francisco, CA.

O157:H7 can be spread from person-to-person, as had been reported in child day-care settings. The Agency concluded that raw ground beef products present a significant public health risk because they are frequently consumed after preparation, (e.g., cooking hamburger to a rare or medium rare state) that does not destroy *E. coli* O157:H7 organisms that have been introduced below the product's surface by chopping or grinding.

In 1999, FSIS published a *Federal Register* notice to update its policy concerning raw beef products contaminated with *E. coli* O157:H7 (64 FR 2803, Jan. 19, 1999). In the notice, FSIS stated that the public health risk presented by beef products contaminated with *E. coli* O157:H7 is not limited to raw ground beef products. In the notice, FSIS announced that "given the low infectious dose of *E. coli* O157:H7 associated with foodborne disease outbreaks and the very severe consequences of an *E. coli* O157:H7 infection, the Agency believes that the status under the FMIA of beef products contaminated with *E. coli* O157:H7 must depend on whether there is adequate assurance that subsequent handling of the product will result in food that is not contaminated when consumed" (64 FR 2803). The Agency also explained that "in evaluating beef products contaminated with *E. coli* O157:H7, intact cuts of muscle that are to be distributed for consumption as intact cuts should be distinguished from non-intact products as well as from intact cuts of muscle that are to be further processed into non-intact product prior to distribution for consumption" (64 FR 2803, 2804). Intact beef cuts of muscle include steaks, roasts, and other intact cuts in which the meat interior remains protected from pathogens migrating below the exterior surface and are not considered adulterated if the outer surface is contaminated with STEC. FSIS stated that, with the exception of intact cuts of muscle that are to be distributed for consumption as intact cuts, an *E. coli* O157:H7-contaminated beef product must not be distributed until it has been processed into a RTE product. FSIS, therefore, deemed *E. coli* O157:H7 as an adulterant of non-intact raw beef products and intact cuts that are to be further processed into non-intact raw products before being distributed for consumption.

In September 2011, FSIS determined that six additional STEC serogroups (O26, O45, O103, O111, O121, and O145) are also adulterants of raw non-intact beef products and product components used to manufacture these products (76 FR 58157, Sept. 20, 2011). In announcing this determination, the

Agency explained that while over 50 STEC serogroups have been associated with human illness, U.S. Centers for Disease Control and Prevention (CDC) data shows that over 70 to 83 percent of confirmed, serogrouped, non-O157 STEC illnesses are caused by these six STEC serogroups (76 FR 58157, 58158). Available data at that time, including information from outbreaks and human illnesses, showed that, like *E. coli* O157:H7, these six STEC were associated with serious illnesses and that they have a relatively low infectious dose. There is also evidence that these strains have very similar characteristics to *E. coli* O157:H7 strains in that they too can survive ordinary consumer cooking practices for raw, non-intact beef products. Thus, FSIS determined that raw, non-intact beef products and intact cuts to be further processed into non-intact products that are contaminated with *E. coli* O157:H7 and pathogenic STEC O26, O45, O103, O111, O121, and O145 are adulterated under the FMIA because they contain a poisonous or deleterious substance that may render them injurious to health (21 U.S.C. 601(m)(1)) (76 FR 31975). The Agency also determined that raw, non-intact beef products that are contaminated with these pathogens are unhealthful and unwholesome (21 U.S.C. 601(m)(3)) (76 FR 31975).

Petitions to Declare Certain Salmonella Serotypes as Adulterants

As noted above, FSIS historically has not considered raw meat and poultry products to be adulterated when they contain *Salmonella*, based on the assumption that ordinary methods of cooking and preparing these products kill *Salmonella*. In response to petitions submitted by the Center for Science in the Public Interest (CSPI) in 2011 and 2014, FSIS evaluated whether certain antibiotic-resistant (ABR) *Salmonella* serotypes could be considered as adulterants in raw meat and raw poultry products under the FMIA and PPIA. The 2011 petition asked FSIS to declare four strains of ABR *Salmonella* as adulterants when found in ground meats and poultry.[6] FSIS denied the 2011 petition without prejudice on July 31, 2014. In its response, FSIS explained that the data available at that time "did not support giving the four strains of ABR *Salmonella* identified in the petition a different status as an adulterant in raw ground beef and raw ground poultry than *Salmonella* strains that are susceptible to antibiotics."[7]

[6] CSPI petition #11-06 (May 25, 2011), "Petition for an Interpretive Rule Declaring Specific Strains of Antibiotic Resistant *Salmonella* to be Adulterants Withing the Meaning or 21 U.S.C. 601(m)(1) and (2)(a) and 21 U.S.C. 453(g)(1) and (2)(a)." FSIS final response July 31, 2014.

[7] FSIS final response to petition #11-06, p. 1.

The response stated that additional data on the characteristics of ABR *Salmonella* are needed to determine whether certain strains could qualify as adulterants under the FMIA and PPIA. The response also noted that because the Agency's denial was without prejudice, the petitioner was not precluded from submitting a revised petition that includes additional information to support the requested action.

The CSPI 2014 petition was a refiling of the 2011 petition and asked that FSIS declare certain strains of ABR *Salmonella* as adulterants in all meat and poultry products based on evidence attained since 2011 that, according to the petition, demonstrates both ground and intact poultry products are associated with outbreaks from ABR *Salmonella*.[8] Based on the data available at the time, FSIS denied the 2014 petition without prejudice on February 7, 2018. In its response to the petition, the Agency concluded that, with respect to its status as an adulterant, "*Salmonella* does not appear to present the same issues as STEC, regardless of whether it is resistant or susceptible to antibiotics."[9] The Agency noted that the consumer studies submitted in support of the petitions did not demonstrate that the study participants had expressed a specific preference or intent to prepare or consume a meat or poultry product in a manner that is not properly cooked and did not describe specific characteristics of a meat or poultry product that consumers might mistakenly associate with proper cooking, such as a rare or medium rare hamburger. Thus, based on the consumer studies and other information on *Salmonella* available at that time, FSIS determined that it "had no basis to conclude that either ABR-*Salmonella* or non-ABR *Salmonella* would render injurious to health what consumers consider to be properly cooked meat or poultry."[10]

FSIS also considered whether certain *Salmonella* serotypes should be considered as adulterants in all meat and poultry products in response to a petition submitted by Marler Clark LLP on behalf of several individuals and consumer advocacy organizations in January 2020.[11] The petition asked FSIS to

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[8] CSPI petition #14-01 (October 1, 2014), "Request for an Interpretive Rule Declaring Certain Antibiotic-Resistant Strains of *Salmonella* to be Adulterants" and FSIS final response (February 7, 2018) at: https://www.fsis.usda.gov/federal-register/petitions/request-interpretive-rule-declaring-certain-antibiotic-resistant-strains

[9] FSIS final response to petition #14-06, p. 6. Available at: https://www.fsis.usda.gov/federal-register/petitions/request-interpretive-rule-declaring-certain-antibiotic-resistant-strains

[10] FSIS final response to petition #14-06, p. 7. Available at: https://www.fsis.usda.gov/federal-register/petitions/request-interpretive-rule-declaring-certain-antibiotic-resistant-strains

[11] Marler Clark LLP petition # 20-01 "Petition for an Interpretive Rule Declaring 'Outbreak' Serotypes of *Salmonella enteritica* subspecies to be Adulterants" dated January 19, 2020. Available at: https://www.fsis.usda.gov/policy/petitions/petition-interpretive-rule-related-certain-salmonella-serotypes

declare 31 *Salmonella* serotypes that have been associated with foodborne illness outbreaks to be adulterants of all meat and poultry products subject to the FMIA and the PPIA.

In its response to the petition, FSIS explained that while the Agency agrees that it needs to rethink its existing *Salmonella* strategy to reduce human illnesses associated with poultry, it does not believe that there is sufficient data available at this time to support the sweeping actions requested in the petition.[12] The response noted that, as announced in October 2021[13], FSIS is in the process of re-evaluating its approach to controlling *Salmonella* in poultry and is considering many of the points and arguments made in the petition as part of its re-evaluation. The response also noted that while FSIS has traditionally viewed *Salmonella* as "naturally occurring" in food animals, the Agency is reassessing this interpretation as part of its *Salmonella* in poultry initiative and considering whether *Salmonella* should be considered an adulterant in any poultry products. The response stated that in this consideration, FSIS is relying on the factors it identified when the Agency declared certain STEC strains to be adulterants in raw non-intact beef products and intact source materials for raw ground beef.

On January 25, 2021, CSPI and other consumer advocacy organizations and individuals petitioned FSIS to establish enforceable standards targeting *Salmonella* types of greatest public health concern and all *Campylobacter* in poultry, and to require supply chain controls.[14] With respect to the request to establish enforceable performance standard, the petition asserts that FSIS should focus specifically on the types of *Salmonella* of greatest public health concern and declare the most virulent *Salmonella* strains to be adulterants in raw poultry products. The petition also requests that FSIS employ enforceable quantitative thresholds to ensure that any *Salmonella* or *Campylobacter* that is permitted on poultry products is maintained at levels low enough to be less likely to cause human illness. The petition asserts that 21 U.S.C. 453(g)(1) authorizes FSIS to deem poultry products that contain virulent

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[12] FSIS Final Response to Petition #20-01, May 31, 2022. Available at: https://www.fsis.usda.gov/policy/petitions/petition-interpretive-rule-related-certain-salmonella-serotypes

[13] United States Department of Agriculture. (October 19, 2021). USDA Launches New Effort to Reduce *Salmonella* Illness Linked to Poultry. https://www.usda.gov/media/press-releases/2021/10/19/usda-launches-new-effort-reduce-salmonella-illnesses-linked-poultry; *see also* Food Safety and Inspection Service. (December 2, 2021). Pilot Projects: *Salmonella* Control Strategies. https://www.fsis.usda.gov/inspection/inspection-programs/inspection-poultry-products/reducing-salmonella-poultry/pilot

[14] CSPI petition #21-01, "Petition to Establish Enforceable Standards Targeting *Salmonella* Types of Greatest Public Health Concern while Reducing all *Salmonella* and *Campylobacter* in Poultry, and to Require Supply Chain Controls" (January 25, 2021) at: https://www.fsis.usda.gov/policy/petitions/petition-submitted-center-science-public-interest

Salmonella strains and that contain pathogens levels above a set threshold to be adulterated under the PPIA.

FSIS is currently reviewing the 2021 CSPI petition and supporting information. As noted above, FSIS is in the process of reevaluating its approach to controlling *Salmonella* in poultry. Because the actions requested in the 2021 CSPI petition are directly related to this effort, FSIS is considering the petition and supporting information as part of its reevaluation.

Assessing a Pathogen's Status as an Adulterant in a NRTE Product

As noted above, while certain STEC have been the only pathogens to date that are considered adulterants in a raw product, certain other pathogens may also exhibit characteristics that would meet the standard to be considered as adulterants in a specific raw product. Thus, if FSIS became aware of evidence to show that a specific pathogen and product pair presents a significant public health risk, the Agency would consider the factors it identified to distinguish certain STEC from other pathogens as adulterants in raw, non-intact beef products and intact cuts to be further processed into non-intact beef products to determine the pathogen's status as an adulterant. The parallel to STEC in beef is not intended to be a direct comparison between non-intact raw beef products and other raw products or about the specific preparation methods between non-intact raw beef and other raw products. The intent is to identify the criteria that were used to determine that certain STECs are adulterants in non-intact beef and apply these criteria to assess whether there are other pathogens that should be considered as adulterants when present in a specific raw product. Specifically, the Agency would consider whether certain pathogen serogroups or types have been associated with human illnesses; whether the pathogen has a relatively low infectious dose; whether the pathogen can cause serious human illnesses; and whether traditional or ordinary cooking practices associated with the specific raw products are sufficient to destroy the pathogen.

II. **NRTE Breaded Stuffed Chicken Products**

NRTE breaded stuffed chicken products contain raw, comminuted chicken breast meat, trim, or whole chicken breast meat, but the finished product is heat-treated only to set the batter or breading

on the exterior of the product, which may impart an RTE appearance.[15] The product typically is stuffed with ingredients, such as a raw vegetable, butter, cheese or meat such as ham, and is typically cooked by household consumers from a frozen state. NRTE breaded stuffed chicken products do not include other types of stuffed products that are not breaded, such as turducken or whole stuffed chickens. NRTE breaded products that are not also stuffed, such as chicken nuggets and other par-fried products are not included in this product type. Only NRTE products that are both breaded and stuffed are the subject of this policy.

NRTE breaded stuffed chicken products contain raw poultry and thus may contain pathogens, such as *Salmonella*. However, because the product may appear fully cooked, some consumers may only reheat the product for aesthetic or palatability purposes rather than subject it to cooking sufficient to kill pathogenic bacteria. NRTE breaded stuffed chicken products are also typically cooked from a frozen state, which increases the risk that they will not reach an internal temperature needed to destroy *Salmonella* organisms that may be in the product. While NRTE chicken nuggets and other par-fried breaded products that are not stuffed may also have a cooked appearance, the focus of this document is on NRTE breaded stuffed chicken products because these stuffed products are thicker in diameter and have a different composition than other par-fried breaded products, which can make effective cooking of NRTE breaded stuffed chicken products more challenging. In addition, it may be difficult for a consumer to determine an accurate internal temperature of these products because they contain multiple ingredients that may cook at different rates. FSIS has recommended in the past that consumers check the temperature at multiple locations throughout the product, but this is not always practical or accurate.[16] In addition, NRTE breaded stuffed chicken products have been associated with a number of *Salmonella* illness outbreaks in the United States.

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[15] FSIS Directive 5300.1, Revision 1. Managing the Establishment Profile in the Public Health Information System (Oct 19, 2016). See attachment 2 "NRTE Stuffed Chicken Products that appear RTE." Available at: https://www.fsis.usda.gov/policy/fsis-directives/5300.1

[16] Smith, K.E., Medus, C., Meyer, S.D., Boxrud, J.D., Leano, F., Hedburg, C., Elfering, K., Braymen, C., Bender, J.B., Danila, R.N. 2008. Outbreaks of Salmonellosis in Minnesota (1998 through 2006) Associated with Frozen, Microwaveable, Breaded Stuffed Chicken Products. Journal of Food Protection. 71(10): 2153-2160.

Before 2006, many NRTE breaded stuffed chicken products were marketed as a microwaveable product, and the labeling on the product packaging included instructions for cooking the products in both a microwave and conventional oven. However, as discussed below, information from documented *Salmonella* illness outbreaks associated with NRTE breaded stuffed chicken products from 1998 through 2006 showed that, based on the product's labeling, appearance, and frozen state, most case patients that became ill after consuming these products thought that the product was pre-cooked, and therefore, did not cook it to an internal temperature necessary to destroy pathogens. In response, industry producers have made numerous changes to the labeling of NRTE breaded stuffed chicken products over time to inform consumers that these products are raw and to provide instructions on how to prepare them safely. In addition, industry no longer markets NRTE breaded stuffed chicken products as microwavable products because cooking these products in a microwave oven decreases the chances that they will reach an internal temperature needed to destroy *Salmonella*. From 1998 to 2021, FSIS and public health partners have investigated 14 *Salmonella* illness outbreaks associated with consumption of NRTE breaded stuffed chicken products, which are summarized below and listed in Table 1. An FSIS analysis of all chicken associated outbreaks the Agency identified in the CDC National Outbreak Reporting System (NORS)[17] or in the scientific literature from 1998-2020 found that although NRTE breaded stuffed chicken products account for less than 0.15 percent of the total domestic chicken supply (in 2021, 53.9 million pounds of NRTE breaded stuffed chicken were produced compared to 45.4 billion pounds of raw chicken products overall), outbreaks linked to these products represented approximately five percent of all chicken-associated outbreaks in the United States during this time. (See Appendix A for the list of *Salmonella* outbreak investigations associated with all chicken products from 1998-2020).

Salmonella Illness Outbreak Investigations Associated with NRTE Breaded Stuffed Chicken Products 1998-2016 and FSIS and Industry Response

[17]CDC National Outbreak Reporting System available at: https://www.cdc.gov/nors/index.html

1998-2006 outbreak investigations. From 1998 through 2006, four separate outbreaks of salmonellosis associated with consumption of NRTE breaded stuffed chicken products were identified in Minnesota.[18] In the first outbreak in 1998, 33 *Salmonella* Typhimurium cases were associated with a single brand of raw, frozen, stuffed, breaded, pre-browned, and microwaveable Chicken Kiev product.[19] Of the 33 people who became ill, 3 were hospitalized for a range of 2-3 days. The outbreak duration was 5 months. Most case patients reported that they thought the product was pre-cooked, and most prepared the product in a microwave oven. No case patients reported taking an internal temperature of the product after cooking. In response to the outbreak, the company that produced the product initiated a voluntary recall of the implicated products and made several changes to the product label, such as replacing the words "ready to cook" on the principal display panel with the words "not precooked" and adding "not pre-cooked—cook thoroughly" and "cook to an internal temperature of 165^{o}F" to the cooking instructions on the back of the package.

In the second outbreak in early 2005, four *Salmonella* Heidelberg human illnesses were associated with raw, frozen, stuffed, breaded, pre-browned, and microwaveable chicken products.[20] One elderly case patient was hospitalized for 4 days. The duration of the outbreak was three months. A separate published report noted that additional *Salmonella* cases associated with similar products were also reported in Michigan.[21] In response to the outbreak, FSIS issued a public health alert (PHA) to remind consumers that frozen meat and poultry products must be fully cooked before they are consumed. In addition, the manufacturer modified the labels of the products to include the word "uncooked" and verified the cooking instructions.

In the third outbreak in August 2005 through July 2006, 27 *Salmonella* Enteritidis cases were associated with a variety of raw, frozen, stuffed, breaded, pre-browned, and microwaveable chicken

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[18] Smith K, Medus C, Meyer S. et al. Outbreaks of Salmonellosis in Minnesota (1998 through 2006) Associated with frozen, microwavable, breaded, stuffed chicken products (2008). *Journal of Food Protection, 71*(10), 2153–2160.

[19] Smith, K. *et al*. (2008).

[20] Smith, K. *et al*. (2008).

[21] Response to the Questions Posed by the Food Safety and Inspection Service Regarding Consumer Guidelines for the Safe Cooking of Poultry Products; APPENDIX I. REPORT ON SALMONELLOSIS LINKED TO CONSUMING PROCESSED CHICKEN PRODUCTS IN MINNESOTA AND MICHIGAN: SUMMARY OF A PRESENTATION GIVEN TO NACMCF ON 7 JULY 2005 BY MR. KEVIN ELFERING OF THE MINNESOTA DEPARTMENT OF AGRICULTURE. *Journal of Food Protection, 70*(1), 251-260.

products.[22] The products represented eight product brands produced by three separate companies. *Salmonella* Enteritidis was isolated from intact samples of breaded stuffed chicken products produced in an establishment owned by one of the companies. Of the 27 case patients, 6 were hospitalized. The length of hospitalization ranged from 2 to 30 days. Two elderly case patients were hospitalized for 30 days. Another case patient required surgery for a perforated colon. The duration of the outbreak was 11 months. Nineteen of the 27 case patients used a microwave oven to cook the products and none of the case patients took the internal temperature of the product after cooking it. The establishment that produced the products from which *Salmonella* Enteritidis had been isolated voluntarily recalled 75,800 pounds of frozen, breaded stuffed NRTE chicken entrees.[23] Because of the ongoing nature of this outbreak, FSIS issued a PHA in July 2006 to provide additional information to enable consumers to more readily identify the class of products implicated in the outbreak and to emphasize that they must be cooked to an internal temperature of 165^{o}F.[24] The PHA noted that in addition to the cases in Minnesota, there were at least 34 other human illnesses across the United States associated with the consumption of undercooked chicken entrees.

While the 2005-2006 *Salmonella* Enteritidis outbreak was being investigated, an outbreak of three *Salmonella Typhimurium* illnesses associated with breaded stuffed chicken products was identified.[25] Two of the case patients were hospitalized for 2 days each. The duration of the outbreak was two months. All three case patients microwaved the product, and none used a thermometer to check the internal temperature of the product.

2005-2006 FSIS and industry response. In March 2006, in response to the 2005-2006 *Salmonella* Enteritidis outbreak and recall, FSIS sent a letter to all establishments that produced frozen NRTE breaded stuffed chicken products to strongly recommend that the labeling of these products be modified to emphasize that the products are not cooked. FSIS also recommended that these establishments enhance and validate the cooking instructions to ensure that they address the intended

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[22] Smith, K. *et al*. (2008).

[23] FSIS Recall Release: Indiana Firm Recalls Frozen Stuffed Chicken Entrees Associated with Illnesses (March 10, 2006).

[24] FSIS Issues Public Health Alert for Frozen, Stuffed, Raw Chicken Products (July 2006).

[25] Smith, K. *et al*. (2008).

use by the consumer. FSIS posted the letter to the FSIS website. [26] The letter explained that a statement on the principal display panel of the packaging, such as "Uncooked: For Safety, Must be Cooked to an Internal Temperature of 165 degrees F as Measured by Use of a Thermometer", would be appropriate to help consumers understand the need to safely prepare the product on their part. The letter also stated that in light of the concerns associated with the NRTE breaded stuffed chicken products subject to the recall, establishments were requested to submit their revised labeling to FSIS for evaluation of the necessary modifications and re-approval. The letter noted that if FSIS did not receive the modified labeling submissions by May 1, 2006, the labels for the subject products would be deemed to be rescinded.

In addition to the letter, in March 2006, FSIS made publicly available guidance contained in a March 2006 report of the Subcommittee on Consumer Guidelines for the Safe Cooking of Poultry Products of the National Advisory Committee on Microbiological Criteria for Foods (NACMCF) regarding consumer guidelines for the safe cooking of NRTE breaded stuffed chicken products.[27] The NACMCF recommended, among other things, that consumers should be advised to cook these products to a single minimum internal temperature of 165^{o}F and that microwaving raw poultry from a frozen state is not advisable unless the manufacturer's cooking instructions ensures that they achieve the recommended 165^{o}F end point temperature. The NACMCF also recommended that the principal display panel on the label indicate whether the product is RTE or NRTE and stated that it may be necessary to provide a warning on the label to fully cook the product if the product appears RTE to the consumer. In addition, in April 2006, FSIS issued guidance to establishments that produce NRTE breaded stuffed chicken products on the necessary modifications recommended for the labeling of these products.[28]

In November 2006, FSIS issued instructions to its inspection program personnel (IPP) on how to verify that establishments producing NRTE breaded stuffed chicken product have product labeling

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[26] Letter to industry about the safe handling labeling of uncooked, breaded, boneless poultry products (March 2006) at: https://www.fsis.usda.gov/guidelines/2006-0007

[27] Response to the Questions Posed by the Food Safety and Inspection Service Regarding Consumer Guidelines for the Safe Cooking of Poultry Products. *Journal of Food Protection, 70*(1), 251-260.

[28] Labeling Policy Guidance Uncooked, Breaded, Boneless Poultry Products (April 2006) at: https://www.fsis.usda.gov/guidelines/2017-0001.

consistent with the April 2006 guidance.[29] Specifically, FSIS IPP were instructed to verify that the establishments had new labeling along with adequate validation to support the cooking instructions to be included on the product label.

In response to the 2005-2006 outbreaks and to FSIS guidance, companies that produced NRTE breaded stuffed chicken products modified the product labeling to emphasize that these products are raw and that they should not be microwaved. The companies also modified the product labeling to provide validated instructions for cooking the products in a conventional oven and instructions to cook the product to a minimum internal temperature of 165^{o}F as measured by a food thermometer. However, even with these labeling modifications, *Salmonella* illnesses associated with these products continued to be reported.

2008-2009 outbreak investigations. In 2008 and 2009, FSIS and public health partners investigated 4 separate outbreaks associated with NRTE breaded stuffed chicken products. From February to April 2008, the Minnesota Department of Health (MDH) identified seven *Salmonella* Enteritidis illnesses associated with frozen, pre-browned breaded stuffed chicken products.[30] Five of the seven case patients reported cooking the product in the microwave, even though the cooking instructions did not include microwave preparation and recommended against that method of cooking. In response, FSIS issued a PHA in March 2008 to remind consumers of the importance of following package instructions for NRTE breaded stuffed chicken products and to emphasize that it is important to cook these products in a conventional oven.[31] The PHA identified the establishment that had produced the products associated with the illnesses, and FSIS conducted a Food Safety Assessment (FSA)[32] at the establishment.

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[29] FSIS Notice 75-06, Verification Instructions for Changes in Label Requirements for Uncooked and Raw Frozen, Breaded, Boneless Poultry Products (Nov 13, 2006). Supplemental Q's and A's to Address Products Affected by FSIS Notice 75-06 Verification Instructions for Changes in Label Requirements for Uncooked and Raw Frozen, Breaded, Boneless Poultry Products at: https://www.fsis.usda.gov/guidelines/2006-0008

[30] Minnesota Department of Health Annual Summary of Disease Activity: Disease Control Newsletter. *Salmonella* 2008 at: https://www.health.state.mn.us/diseases/reportable/dcn/sum08/salmonellosis.html

[31] FSIS Public Health Alert, March 29, 2008.

[32] The purpose of an FSA is to conduct a risk-based, targeted review of establishment food safety systems to verify that the establishment is able to produce safe and wholesome meat or poultry products in accordance with FSIS statutory and regulatory requirements (https://www.fsis.usda.gov/policy/fsis-directives/5100.1)

In a separate investigation in October 2008, the MDH reported 14 *Salmonella* illness cases had been linked to raw, frozen, breaded, and pre-browned, stuffed Chicken Cordon Bleu and Chicken Kiev products.[33] MDH reported that the outbreak strain of *Salmonella* was found in four packages of breaded stuffed chicken products recovered from the homes of some of the individuals that were ill and from grocery stores. The outbreak strain was identified as *Salmonella* I 4,[5],12:i:-.[34] An investigation subsequently conducted by FSIS and other public health partners identified 47 illness cases from 17 States associated with the same outbreak strain with 8 reported hospitalizations.[35] Information from case patients identified in Wisconsin found that 9 out of 11 reported that they consumed frozen NRTE breaded stuffed Chicken Kiev or Cordon Bleu products. Four of the Wisconsin case patients reported that they cooked the product in a microwave, and 4 reported that they cooked the product in an oven.

After the investigation was initiated, FSIS issued a PHA due to concerns about illnesses that may be associated with NRTE breaded stuffed chicken products.[36] The PHA reminded consumers of the importance of following package cooking instructions for NRTE breaded stuffed chicken products and general food safety guidelines when handling raw meat or poultry products.

In an additional investigation in May 2009, FSIS received a report from the MDH that 2 *Salmonella* Enteritidis case patients from different households reported eating a NRTE breaded stuffed Chicken Cordon Bleu product that was produced by the same establishment.[37] The illness onsets were reported in February 2009 and April 2009; both less than a week after last consumption of the NRTE breaded stuffed chicken product. The case patients were unable to provide dates of purchase or production. MDH also reported this product was linked to a previous case patient with the same strain by consumption history in September 2008.

In the final 2008- 2009 investigation, FSIS received a report from the MDH of two *Salmonella* Enteritidis cases with an indistinguishable genetic pattern that reported consuming NRTE breaded

[33] MDH News Release; *Salmonella cases linked to raw, frozen chicken entrees* (Oct 8, 2008).
[34] FSIS outbreak investigation case 2009-02.
[35] FSIS outbreak investigation case 2009-02.
[36] FSIS Issues Public Health Alert, October 3, 2008.
[37] FSIS outbreak investigation case 2009-23.

stuffed chicken products that were produced at the same establishment.[38] The product was produced in January 2009 but FSIS was unable to obtain further details because the packaging was partially discarded. An earlier case patient also reported consuming the same product but had no remaining product.

2013 and 2014 outbreak investigations. In 2013 and 2014, FSIS and public health partners investigated 2 separate *Salmonella* illness outbreaks associated with NRTE breaded stuffed chicken product. In August 2013, FSIS was notified of three *Salmonella* Enteritidis cases from Minnesota.[39] The illness onset dates were from April 2013 to July 2013. All three case patients reported consuming various NRTE chicken products produced by two separate establishments prior to illness onset. The Minnesota Department of Agriculture (MDA) collected and tested intact breaded stuffed chicken products from the case patients' homes. Products produced by one of the establishments tested positive for *Salmonella* Enteritidis, *Salmonella* Typhimurium, *Salmonella* Kentucky, and *Salmonella* I 4,12:i:-. A Chicken Cordon Bleu and Bacon and Cheddar product produced by the other establishment tested positive for the same *Salmonella* Enteritidis outbreak strain as the case patients. Two case patients reported cooking the product in the oven but one of them stated that they were not aware that the product was raw. Another case patient reported microwaving the product.

In response to the information obtained from the August 2013 outbreak investigation, FSIS issued an FSIS Notice in June 2014 instructing FSIS Inspection Program Personnel (IPP) to perform a Hazard Analysis Verification (HAV) Task[40] at establishments that produced NRTE breaded stuffed chicken products.[41] The Notice stated that during the 2013 outbreak investigation, FSIS discovered that there are consumers that may be unaware that NRTE breaded stuffed chicken products can be produced as raw frozen products. The Notice explained that the frozen state, labeling, and cooked appearance of these products may cause consumers to falsely believe that such products are precooked. The Notice

[38] FSIS outbreak investigation case 2009-43.
[39] FSIS outbreak investigation case 2013-17.
[40] An HAV task is a verification task performed by IPP focusing on establishments' hazard analyses, pre-requisite programs, and other supporting documentation.
[41] FSIS Notice 31-14, Supplemental Instructions for Performing the Hazard Analysis Verification Task in Establishments that Produce NRTE Stuffed Poultry Products (June 30, 2014).

instructed IPP to verify that establishments producing NRTE breaded stuffed chicken products have appropriately considered the microbial hazards associated with these products and have documentation to support their resulting decisions.

In a separate investigation in August 2014, six *Salmonella* Enteritidis illnesses in Minnesota were associated with NRTE breaded stuffed Chicken Kiev products.[42] The illness onsets ranged from August 17, 2014, to September 27, 2014, and one case patient was hospitalized. In October 2014, the establishment that produced the product initiated a voluntary recall of 28,980 pounds of the product.[43] The product labeling stated in several places that the product was raw and included validated cooking instructions as recommended in the FSIS guidance for labeling NRTE breaded stuffed chicken products. The FSIS recall release associated with the recall emphasized the importance of following package cooking instructions on any NRTE breaded chicken product and to use a thermometer to ensure that the product reaches an internal temperature of 165°F.

2015-2016 outbreak investigations. In 2015 and 2016, FSIS and public health partners investigated three *Salmonella* outbreaks associated with NRTE breaded stuffed chicken products. The MDH, Minnesota Department of Agriculture, CDC, and FSIS investigated two separate *Salmonella* Enteritidis outbreaks associated with NRTE breaded stuffed chicken products produced by different establishments from June 2015 through October 2015.[44,45] One of the outbreaks included five cases from Minnesota with illness onset dates from May 9, 2015, through July 22, 2015.[46] Two of the case patients were hospitalized. All case patients reported consuming various NRTE breaded stuffed chicken products the week before illness onset. All products were produced at the same establishment. In follow-up interviews, two case patients stated that they were aware that the product was raw, three

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[42] *Salmonella* cases linked to raw, frozen chicken entrees (October 23, 2014). Press release by Minnesota Department of Health/Minnesota Department of Agriculture.
[43] FSIS Recall Release (October 24, 2014): Illinois Firm Recalls Chicken Products Due To *Salmonella* Enteritidis Contamination https://www.fsis.usda.gov/recalls-alerts/illinois-firm-recalls-chicken-products-due-possible-salmonella-enteritidis
[44] FSIS *Salmonella* Enteritidis Illness Outbreaks Associated with Raw, Frozen, Stuffed Chicken Products, 2015 After-Action Review Report 2015-11/2015-12 (December 6, 2016) at: https://www.fsis.usda.gov/food-safety/foodborne-illness-and-disease/outbreaks/outbreak-investigations-response
[45] Minnesota Department of Health: *Salmonella* cases linked to raw, frozen, stuffed chicken products (July 2, 2015) at: https://content.govdelivery.com/accounts/MNMDH/bulletins/10d1df0
[46] CDC: Outbreak of *Salmonella* Enteritidis Infections Linked to Raw, Frozen, Stuffed Chicken Entrees Produced by Aspen Foods (Final Update) at: https://www.cdc.gov/salmonella/frozen-chicken-entrees-part2-07-15/index.html

stated that they cooked the product in a conventional oven as instructed on the label, one reported that they used a convection oven/microwave and used a thermometer to confirm that the product reached an internal temperature of 165°F, and one case patient stated that they were not aware that the product was raw and cooked it in a microwave.

In response to the outbreak, the establishment voluntarily recalled approximately 1,978,608 pounds of product in July 2015.[47] In addition, in September 2015, FSIS issued a PHA to inform the public that additional NRTE breaded stuffed chicken products produced by the establishment subject to the July 2015 recall had tested positive for the same *Salmonella* Enteritidis strain associated with the outbreak.[48] In October 2015, the establishment expanded the July 2015 recall to include an additional 561,000 pounds of products implicated by *Salmonella*-positive results matching the outbreak strain to prevent additional illnesses.[49] The labeling of most of the products subject to the recall stated that the product was raw, should not be cooked in a microwave oven, and provided validated cooking instructions. The label also included instructions to cook the product to a minimum internal temperature of 165^{o}F as measured by a food thermometer and included icons and illustration that emphasized these messages.

A separate 2015 outbreak associated with NRTE breaded stuffed chicken produced by a different establishment included 15 cases from 7 states (CT, IL, MN, NH, NY, OK, and WI) with illness onset dates from April 5, 2015, through July 27, 2015. Among 10 case patients with available information, 4 were hospitalized.[50] Information available from eight case patients indicated that seven of the eight cooked the product in a conventional oven and one used a toaster oven.[51] In response, in July 2015, the establishment that produced the implicated product voluntarily recalled approximately

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[47] Aspen Foods Recalls Frozen, Raw, Stuffed and Breaded Chicken Product Due To Possible *Salmonella* Contamination (July 15, 2015) at: https://www.fsis.usda.gov/recalls-alerts/aspen-foods-recalls-frozen-raw-stuffed-breaded-chicken-products-due-possible-0#labels

[48] FSIS Issues Public Health Alert for Stuffed Chicken Products Due to Possible S*al*monella Contamination (September 17, 2015) at: https://www.fsis.usda.gov/recalls-alerts/fsis-issues-public-health-alert-stuffed-chicken-products-due-possible-salmonella

[49] Aspen Foods Recalls Frozen, Raw, Stuffed and Breaded Chicken Product Due To Possible *Salmonella* Contamination (October 2, 2015) at: https://www.fsis.usda.gov/recalls-alerts/aspen-foods-recalls-frozen-raw-stuffed-breaded-chicken-products-due-possible

[50] CDC: Multi-State Outbreak of Drug-Resistant *Salmonella* Enteritidis Infections Linked to Raw, Frozen, Stuffed Chicken Entrees Produced by Barber Foods (Final Update; October 16, 2015) https://www.cdc.gov/salmonella/frozen-chicken-entrees-07-15/index.html.

[51] FSIS outbreak ID 2015-12.

58,320 pounds of various NRTE breaded stuffed chicken products, which was expanded to include additional product for a total of over 1,700,000 pounds of product.[52] The labeling of most of the products subject to the recall clearly stated that the product was raw, should not be cooked in a microwave oven, and provided validated cooking instructions. The label also included instructions to cook the product to a minimum internal temperature of 165^{o}F as measured by a food thermometer and included icons and illustration that emphasized these messages.

In 2016, 5 *Salmonella* Enteritidis cases associated with NRTE breaded stuffed chicken were reported in Minnesota.[53] Three of the 5 case patients reported eating NRTE breaded stuffed chicken products purchased at the same retail store, and 2 of those 3 purchased a product brand that was produced by the same establishment. An FSIS investigation found that the retail store had received the same brand of NRTE breaded stuffed chicken products produced by the same establishment during the time in which case patients reported shopping at the retail store.

2015-2016 FSIS and industry response. In response to the 2015 outbreaks and recalls, FSIS issued NOIEs to the two establishments that produced the products associated with the outbreaks to inform them that FSIS intended to withhold marks of inspection or issue a suspension if they did not respond to FSIS within 3 business days regarding how they have or will implement corrective actions.[54,55] FSIS also conducted intensified sampling in these establishments for *Salmonella*, including sampling of comminuted source material, final product, and production environment surface sampling. Both establishments implemented corrective actions, such as source product testing and application of new interventions during processing, that were validated and verified by FSIS. One of the establishments also implemented product labeling changes.

In February 2016, FSIS instructed FSIS IPP at establishments that produce raw and heat-treated but not fully cooked, not shelf-stable breaded stuffed chicken products to update the establishments' Public Health Information System (PHIS) profile to allow FSIS to determine which establishments

[52] Barber Foods Recalls Stuffed Chicken Products Due to Possible *Salmonella* Enteritidis Contamination (July 12, 2015) at: https://www.fsis.usda.gov/recalls-alerts/barber-foods-recalls-stuffed-chicken-products-due-possible-salmonella-enteritidis.
[53] FSIS outbreak investigation case 2016-06.
[54] NOIE Establishment P-1358, July 10, 2015.
[55] NOIE Establishment P-276, July 10, 2015.

produce NRTE breaded stuffed chicken products that appear RTE.[56] After IPP updated the PHIS profiles, FSIS used the information to schedule a Public Health Risk Evaluation (PHRE)[57] and, if necessary, an FSA at these establishments. FSIS also captured information concerning these establishments' production practices and evaluated whether establishments had reassessed their Hazard Analysis and Critical Control Point (HACCP) plans in response to the recent outbreaks associated with these products (9 CFR 417.4(b)). In addition, the Agency published industry guidance with information on developing validation for labeled cooking instructions for raw and partially cooked, breaded, boneless poultry products.[58]

In 2015-2016, FSIS also held conference calls and worked directly with establishments that produced NRTE breaded stuffed chicken products to modify the product labeling to further emphasize that the product is raw and to ensure that the label included validated cooking instructions. Based on recommendations from FSIS, establishments re-validated the cooking instructions on the product label to ensure that, when prepared as instructed, a NRTE breaded stuffed chicken product would reach an internal temperature needed to destroy *Salmonella* organisms on the interior of the product. FSIS also worked with industry to ensure that the product labels emphasized that these products should not be prepared in a microwave oven.

2016 National Advisory Committee on Meat and Poultry Inspection Recommendations and National Chicken Council Petition

2016 National Advisory Committee on Meat and Poultry Inspection recommendations. In March 2016, a National Advisory Committee on Meat and Poultry Inspection (NACMPI) subcommittee was charged to consider mandatory labeling features for certain NRTE meat and poultry products that appear RTE.[59] The subcommittee met on March 29, 2016, and issued a report that provided

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[56] FSIS Notice 15-16, *Profile Update In Establishments That Produce Not-Ready-To-Eat Stuffed Chicken Products That Appear Ready-To Eat* (February 18, 2016).

[57] The PHRE is an analysis of establishment performance based on "For-cause" and "Routine risk-based" criteria, https://www.fsis.usda.gov/policy/fsis-directives/5100.4

[58] Information on Validation of Labeled Cooking Instructions for Products Containing Raw or Partially Cooked Poultry (February 2017) at: https://www.fsis.usda.gov/guidelines/2017-0017

[59] National Advisory Committee on Meat and Poultry Inspection, Subcommittee #2 Consideration of Mandatory Labeling Features for Certain Processed Not Ready to Eat Meat and Poultry products. March 26, 2016. (https://www.fsis.usda.gov/news-and-events/events-meetings/2016-national-advisory-committee-meat-and-poultry-inspection-nacmpi).

recommendations on labeling and other measures to prevent illnesses associated with these products.[60] The report recommended, among other things, that the labels of NRTE meat and poultry products that appear RTE include statements, such as "Raw" and "Uncooked" to differentiate these products from RTE products, and that they should also include validated cooking instructions that include the method of cooking, the endpoint temperature for safety, and an instruction to use a thermometer to measure the endpoint. The report also recommended that the cooking instructions include a disclaimer to not use a microwave, if applicable. Moreover, it recommended that FSIS conduct consumer focus groups to understand the optimal messaging and design of packaging to ensure consumers properly understand that NRTE products need to be cooked for lethality. The report further stated that FSIS should consider creating a standard of identity for these products if illnesses continue after labeling changes are made.

2016 National Chicken Council petition. In May 2016, the National Chicken Council (NCC) submitted a petition requesting FSIS to adopt regulations that would define and establish labeling requirements for NRTE breaded stuffed chicken products that appear RTE.[61] The petition also requests that FSIS issue a guidance document for developing and communicating validated cooking instructions that would incorporate the NCC's *Best Practices for Cooking Instruction Validation for Frozen NRTE Stuffed Chicken Breast Products*.[62] The petition requests that FSIS establish regulations to require, among other things, that the product name for NRTE breaded stuffed chicken products include the term "raw;" that the principal display panel on the product packaging include statements and icons to signal that the product is raw and should not be cooked in a microwave; and that the labeling provide validated cooking instructions that include a "do not microwave" icon and state that the product must be cooked to a specified endpoint temperature as measured by a food thermometer. FSIS received two letters in support of the petition, one from an industry trade association and one from a consumer

[60] Subcommittee #2 Consideration of Mandatory Labeling Features for Certain Processed Not Ready to Eat Meat and Poultry Products (March 2016) (https://www.fsis.usda.gov/sites/default/files/media_file/2021-02/NRTE-Labeling.pdf).
[61] National Chicken Council petition #16-03, "Petition to Establish Regulations for the Labeling and Validated Cooking Instructions for Not-Ready-to-Eat Stuffed Chicken Breast Products That Appear Ready-to-Eat" dated May 24, 2016 available at: https://www.fsis.usda.gov/federal-register/petitions/establish-labeling-requirements-not-ready-eat-stuffed-chicken-products
[62] Attachment 1, National Chicken Council petition #16-03.

advocacy organization.[63] The consumer advocacy organization expressed general support for new labeling requirements for NRTE breaded stuffed chicken products but noted that determining consumer compliance with labeling instructions is hard to assess and that the chicken industry should not rely on labeling alone as a measure to prevent human illnesses associated with these products. The industry trade association believed that the labeling requirements requested in the petition would enhance food safety by reinforcing proper consumer handling of these products and encouraged FSIS to move forward with rulemaking consistent with the petition.

To support the requested action, the petition submitted the results of a 2009 online study conducted by the NCC. The study included the results of 1,000 online interviews to assess consumers' understanding of the raw nature of NRTE breaded stuffed chicken products that appear RTE based on a 2008 "generic old copy" of a NRTE breaded stuffed chicken label that did not include the labeling features requested in the petition and a 2009 "generic new copy" of a NRTE breaded stuffed chicken product label that included the labeling requirements requested in the petition. The study found that when compared to the labeling features in the 2008 generic label, the mandatory labeling features in the 2009 generic label increased the study participants' awareness of the raw state of the product and increased the number of participants who noticed the mention of a food thermometer. As additional support, the petition referenced the labeling recommendations included in the 2006 NACMCF report discussed above as well as the 2016 NACMPI report recommendations that FSIS require NRTE products that appear RTE to bear mandatory labeling statements and include validated cooking instructions.

When FSIS received the 2016 NCC petition, most manufacturers of NRTE breaded stuffed chicken products had voluntarily incorporated the labeling features recommended by the 2016 NACMPI subcommittee and requested in the 2016 NCC petition in response to the outbreaks associated with these products. However, as discussed below, consumer behavior research results

[63] Letter from Safe Food Coalition dated September 30, 1996 at: https://www.fsis.usda.gov/sites/default/files/media_file/2020-07/16-03-Support-Ltr-093016.pdf and Letter from American Frozen Foods Institute dated August 17, 2016 at: https://www.fsis.usda.gov/sites/default/files/media_file/2020-07/16-03-Support-Ltr-081716.pdf

from 2020 found that even when NRTE breaded stuffed chicken product labels included features recommended by the NACMPI subcommittee and requested in the 2016 NCC petition, twenty-two percent of the study participants were still confused about the raw nature of the product.

Consumer Behavior Research

2020 Meal Preparation Experiment. In September 2020, FSIS published a final report on a consumer research study that examined consumers' use of a food thermometer to check doneness of raw stuffed chicken products prepared from a frozen state.[64] FSIS had contracted with RTI International (RTI) and its subcontractor, North Carolina State University (NCSU), to conduct five separate iterations of a meal preparation study to evaluate consumer food handling behaviors in a test kitchen. The study examining participants' meal preparation related to NRTE breaded stuffed chicken products was the third iteration of the study. It was conducted in a test kitchen facility with individuals who self-reported preparing NRTE breaded stuffed chicken products when cooking at home. The NRTE breaded stuffed chicken product used in the study was packaged to resemble a commercially available product and included the labeling features that manufacturers have voluntarily incorporated into the labeling: i.e., the term "raw" was prominently displayed on the front and back of the product packaging; the principal display panel included statements and icons to signal that the product is raw and should not be cooked in a microwave; and the labeling provided validated cooking instructions that included a "do not microwave" icon as well as icons and instructions to cook the product in a conventional oven to an internal temperature of 165^{o}F as measured by a food thermometer.[65]

A short video, meant to simulate a real news segment on safely preparing frozen NRTE foods, was played for some of the study participants (referred to as "the intervention group") as they sat in the waiting room at the start of their appointment. The segment was included as part of a looped video containing six separate news segments on current news topics. The food safety news segment communicated that although frozen NRTE foods may appear RTE, they are not fully cooked, and the endpoint temperature should be checked with a food thermometer to ensure safety. The segment

[64] Final Report: Food Safety Consumer Research Project: Meal Preparation Experiment on Raw Stuffed Chicken Breasts (September 23, 2020) at: https://www.fsis.usda.gov/sites/default/files/media_file/2021-04/fscrp-yr3-nrte-final-report.pdf
[65] Figure 2-2 Packaging for NRTE Chicken Product Used in Meal Preparation Study.

showed a variety of frozen NRTE foods, including NRTE breaded stuffed chicken products and bagged frozen corn being prepared in the meal preparation study as well as products not being prepared in the study. The control group was exposed to a similar news segment video loop that did not include the segment on food safety. The study had the capacity to include up to 400 participants in each iteration of the meal preparation experiment. The study randomly assigned half of the participants (n = 200) to the treatment group and the remaining 200 participants to the control group. Observations were conducted from April 29, 2019, to September 5, 2019. A final report was issued on September 23, 2020.

With respect to NRTE breaded stuffed chicken products, the study found that consumers may confuse NRTE frozen foods with RTE products. Nearly a quarter of all participants preparing frozen foods were not sure if the products were raw or fully cooked despite reading the preparation instructions on the product label. Twenty-two percent of participants were unaware that the NRTE frozen chicken product they prepared was raw. They believed it was either fully cooked, partially cooked, or were unsure. Eleven percent of the participants incorrectly believed the product was fully cooked. Nearly all study participants had prior experience preparing chicken nuggets. Thus, the pre-browned breaded appearance of the NRTE breaded stuffed chicken products may have also led participants to believe that these stuffed products can be handled the same as other breaded chicken products that are RTE. Seventy-six percent of participants said they would buy NRTE breaded stuffed chicken products for their children to prepare at home.

Ninety-nine percent of all participants self-reported that they had read the manufacturer's instructions for the NRTE breaded stuffed chicken products, which instructed consumers to use a food thermometer to check that the chicken reached a safe internal temperature of 165°F. Seventy-seven percent of participants who were not shown the video used a food thermometer to check that at least one chicken breast reached a safe internal temperature of 165°F, and 75 percent of those participants successfully cooked the chicken breast to 165°F. Eight-eight percent of participants who were shown the video used a food thermometer to check the temperature of at least one chicken breast. Although the rate of thermometer use was higher among the intervention group compared with the control group, the difference was not significantly different. Participants who used other methods to determine

doneness relied on time, visual cues, and touch. Although most participants reported owning a food thermometer at home, 38 percent reported not using their food thermometer at home to check that NRTE breaded stuffed chicken products were properly cooked. Thus, for some participants, their behavior in the test kitchen differed from their typical practice.

The researchers also observed participants throughout the meal preparation to determine whether they adhered to recommended handwashing practices. For purposes of the study, a handwashing attempt was considered successful based on CDC's criteria--wet hands with water; rub hands with soap for at least 20 seconds; rinse hands with water; and dry hands using a clean, one-use towel. The study found that approximately 72 percent of participants attempted to wash their hands before beginning meal preparation. Among handwashing attempts, 5 percent of attempts contained all steps of correct handwashing and were considered successful according to the CDC's criteria. However, during meal preparation, handwashing was attempted only 5 percent of the time that it was required (e.g., after touching the NRTE chicken product), and there were no successful attempts. The study concluded that the small number of handwashing attempts during meal preparation of NRTE breaded stuffed chicken products is likely attributable to participants preparing a raw frozen breaded chicken product rather than fresh raw poultry. Thus, the appearance of NRTE breaded stuffed chicken products and the fact that they are typically cooked from a frozen state may contribute to *Salmonella* cross contamination in the home.

2022 Study on Appliances Used to Prepare NRTE Breaded Stuffed Chicken Products. In December 2022, the CDC published a report on a study that describes the demographic characteristics of persons who prepare NRTE breaded stuffed chicken products and which appliances they use to prepare them.[66] In the study, to assess types of cooking appliances used to prepare NRTE breaded stuffed chicken products, members of an internet research panel were asked to identify which appliances they use to prepare these products. Respondents could choose more than one appliance. Of

[66]Marshall, K.E., Canning, M., Ablan, M., Crawford T.N., Robyn, M. Appliances Used by Consumers to Prepare Frozen Stuffed Chicken Products-United States, May-July 2022. Morb Mortal Wkly Rep Dec 2,2022; 71(48);1511–1516. Available at: http://dx.doi.org/10.15585/mmwr.mm7148a2

the 2,546 panel members that reported preparing NRTE breaded stuffed chicken products, approximately 80 percent reported using an oven as one of the cooking appliances, while 54 percent reported that they prepared these products using appliances other than or in addition to ovens. Although the labeling of NRTE breaded stuffed chicken products typically includes instructions to cook the product in an oven and warns consumers not to cook them in a microwave, approximately 30 percent of the respondents who reported preparing NRTE breaded stuffed chicken products reported using air fryers, 20 percent reported using microwaves, approximately 14 percent reported using toaster ovens, and approximately 4 percent reported using another appliance. The study found that respondents with lower incomes and who live in mobile types of homes reported lower oven use and higher microwave use.

The study noted that current measures to prevent *Salmonella* infections linked to contaminated NRTE breaded stuffed chicken products primarily rely on consumers' ability to identify that they are raw, follow and adequately cook the products according to validated cooking instructions, and to verify the product's internal temperature using a food thermometer. The researchers stated that the survey findings highlight some possible challenges consumers may face preparing NRTE breaded stuffed chicken products safely and the need for additional action. The study suggests that, given the percentage of respondents who reported using an appliance other than an oven to prepare NRTE breaded stuffed chicken products, and socioeconomic characteristics of respondents with lower oven usage, e.g., oven use was lower among respondents with household income <$25,000 (68.9%), and who lived in mobile homes or other portable types of homes (66.5%), companies that produce these products could consider implementing interventions that rely less on labeling and consumer preparation practices to ensure that these products are safe when consumed. The study noted that persons who live in mobile or other portable types of homes might have less or insufficient space for a conventional oven and that appliances like microwaves are small, often portable, and cost less to own and operate than an oven. According to the study, these findings suggest that economic and other factors might influence some groups' access to recommended cooking appliances.

2021 Salmonella Illness Outbreak, NACMPI Subcommittee Recommendations, and NCC Petition Supplement

2021 *Salmonella* illness outbreak. From April through August 2021, state public health officials, the CDC, and FSIS investigated a multistate outbreak of *Salmonella* Enteritidis illnesses linked to NRTE breaded stuffed chicken products.[67,68] Epidemiologic, laboratory, and traceback data showed that NRTE breaded stuffed chicken products produced by a single establishment were associated with the illnesses. The outbreak included 36 cases from 11 States with illness onset dates from February 21, 2021, to August 16, 2021. Of the 27 case patients interviewed, 14 (52 percent) reported preparing and eating NRTE frozen breaded stuffed chicken products. Of 32 case patients with information available (out of 36 total cases), 12 were hospitalized. No deaths were reported.

The labeling of the products associated with the outbreak stated: the product was raw on the front and back of the packaging; included statements and icons to signal that the product is raw and should not be cooked in a microwave oven; and provided validated cooking instructions that included a "do not microwave" icon as well as icons and instructions to cook the product in a conventional oven to an internal temperature of 165^{o}F as measured by a food thermometer. However, some of the case patients reported that they did not follow the manufacturer's cooking instructions on the label. Some case patients reported that they cooked the product in a microwave oven, air fryer, or for a shorter time than instructed for a conventional oven, and they did not use a food thermometer to check that the product reached an internal temperature of 165^{o}F, as instructed on the product label.

The MDA conducted retail product sampling of these products as part of the investigation and isolated the outbreak strain. Based on the strong link between epidemiologic information and product sampling results, FSIS issued a Public Health Alert (PHA) on June 2, 2021, to inform the public that some of the ill patients in the outbreak had reported eating NRTE breaded stuffed chicken prior to illness

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[67] USDA, FSIS: *Salmonella* Enteritidis Outbreak Linked to Frozen, Raw, Breaded, Stuffed, Chicken Products; Outbreak Investigation After Action Review, Report 2021-07 at: https://www.fsis.usda.gov/sites/default/files/media_file/2022-04/FSIS-After-Action-Review-2021-07.pdf

[68] CDC: *Salmonella* Outbreak Linked to Raw Frozen Breaded Stuffed Chicken Products (October 13, 2021) at: https://www.cdc.gov/salmonella/enteritidis-06-21/index.html

onset.[69] FSIS traced the product purchased by one ill patient to an FSIS-regulated establishment, and on August 9, 2021, the establishment voluntarily recalled approximately 59,251 pounds of the affected products.[70]

Table 1: Summary of *Salmonella* Outbreak Investigations Associated with NRTE Breaded Stuffed Chicken products 1998-2021

Year	Serotype	Illnesses	Hospitalization	Recall/PHA
1998	Typhimurium	33	3	Recall
2005	Heidelberg	4	1	PHA
2005- 2006	Enteritidis	27	6	Recall and PHA
2006	Typhimurium	3	2	
2008	Enteritidis	7	2	PHA
2008-2009	I 4,[5],12:i:-	47	8	PHA
2009	Enteritidis	2		
2009	Enteritidis	2		
2013	Enteritidis	3		
2014	Enteritidis	6	1	Recall and PHA

[69] FSIS Issues Public Health Alert for Frozen, Raw, Breaded Stuffed Chicken Products Due to Possible *Salmonella* Contamination (June 2, 2021) at: https://www.fsis.usda.gov/recalls-alerts/fsis-issues-public-health-alert-frozen-raw-breaded-stuffed-chicken-products-due

[70] Serenade Foods Recalls Frozen, Raw, Breaded, Stuffed Chicken Products Due to Possible *Salmonella* Contamination (August 9, 2021) at: https://www.fsis.usda.gov/recalls-alerts/serenade-foods-recalls-frozen-raw-breaded-stuffed-chicken-products-due-possible

2015	Enteritidis	5	2	Recall
2015	Enteritidis	15	4	Recall and PHA
2016	Enteritidis	5		
2021	Enteritidis	36	12	Recall and PHA

Note: Outbreak investigation data from FSIS at the time the investigations were closed

2021 NACMPI Recommendations. On August 27, 2021, FSIS announced that the NACMPI would hold a virtual meeting to consider, among other things, issues related to NRTE breaded stuffed chicken products.[71] The virtual public meeting was held on September 27 and 28, 2021, and a subcommittee was charged to consider actions FSIS should take to prevent and reduce illnesses associated with the handling or consumption of NRTE breaded stuffed poultry products that may appear RTE to consumers.[72] In presenting the charge to the subcommittee, FSIS noted the history of outbreak investigations associated with these products, including the outbreak that resulted in the August 2021 recall, and that these products are labeled as raw and include validated cooking instructions. The Agency also reviewed the results of the consumer research discussed above and noted that FSIS had been petitioned by the NCC in 2016 to establish labeling requirements for NRTE breaded stuffed chicken products and to issue guidance for developing validated cooking instructions. In its charge, FSIS asked the subcommittee to consider several questions on possible measures to address human illnesses associated with NRTE breaded stuffed chicken products.

In a September 28, 2021, report, the subcommittee provided several recommendations that primarily focus on the labeling of NRTE breaded stuffed chicken products. The subcommittee

[71] National Advisory Committee on Meat and Poultry Inspection, Notification of Public Meeting (86 FR 48115, August 27, 2021) at: https://www.fsis.usda.gov/sites/default/files/media_file/2021-08/FSIS-2021-0019.pdf

[72] 2021 National Advisory Committee on Meat and Poultry Inspection Public Meeting at: https://www.fsis.usda.gov/news-events/events-meetings/national-advisory-committee-meat-and-poultry-inspection-nacmpi-public

recommended that FSIS re-verify that companies continue to voluntarily label NRTE breaded stuffed chicken products as raw in several places on the label and that labels of these products include validated cooking instructions. The subcommittee also recommended that FSIS update the 2006 labeling guidance to warn consumers not to use microwaves and air fryers if validated instructions are not provided for these methods and to cook the product to a minimum of 165°F as measured using a food thermometer.[73] The subcommittee further recommended that FSIS add label verification for these products as a recurring task for inspectors and review labels from the 2021 outbreak. In addition, the subcommittee recommended that FSIS require establishments that produce these products to reassess their HACCP plans in light of the outbreaks and encouraged FSIS to conduct targeted consumer outreach regarding these types of products, including creating an FSIS webpage highlighting NRTE breaded stuffed chicken products. The subcommittee did not reach consensus on whether FSIS should conduct exploratory sampling for indicator organisms or pathogens or whether it should conduct sampling for *Salmonella* for these products. The subcommittee also did not recommend that FSIS require that establishments apply a lethality treatment to ensure that all NRTE breaded stuffed chicken products are RTE. The subcommittee agreed with the 2016 NCC petition's request for FSIS to establish requirements for the labeling of NRTE breaded stuffed chicken products and publish industry guidance explaining how to validate cooking instructions for such products and recommended that FSIS take such action.

2022 NCC petition supplement. On February 25, 2022, the NCC submitted a supplement to update its 2016 petition to reflect updates in what the NCC stated was the collective understanding of NRTE breaded stuffed chicken products. Among the updates was a request to establish required specifications for color, shapes, and font sizes for certain labeling statements and icons; a request to require an additional "do not air fry" statement and icon to the product label; and a request to require a website URL, QR code, or similar mechanism on the label that takes the consumer to a webpage that includes a video demonstrating proper cooking methods. The 2022 supplement also requested that the

[73] National Advisory Committee on Meat and Poultry Inspection: Subcommittee II Stuffed Not-Ready-To-Eat Poultry Products (September 28, 2021) at: https://www.fsis.usda.gov/sites/default/files/media_file/2021-10/Subcommittee_II_Stuffed_Not_Read-to-Eat_Poultry_Products_9-28-21_final_Report.pdf

regulations allow statements that emphasize that the product should only be cooked in a conventional oven to be modified to reflect any additional validated cooking instructions, e.g., “do not air fry” could be modified to provide validated air fryer cooking instructions.

III. Evaluation of the Status of *Salmonella* in NRTE Breaded Stuffed Chicken Products under the PPIA

FSIS has carefully considered the 2021 NACMPI subcommittee recommendations on actions the Agency could take to prevent and reduce illnesses associated with NRTE breaded stuffed chicken products as well as the issues raised in the NCC petition and supplement. In light of the 2021 *Salmonella* outbreak and earlier outbreaks associated with these products, the Agency has concluded that the recommendations, which focus primarily on product labeling and consumer handling practices, are unlikely to be effective in preventing additional foodborne illnesses associated with NRTE breaded stuffed chicken products.

Although the labeling of NRTE breaded stuffed chicken products has undergone significant changes over time to better inform consumers that the products are raw and to provide instructions on how to prepare them safely, these products continue to be associated with *Salmonella* illness outbreaks. Information from outbreak investigations found that some ill persons were not aware that the product was raw and did not follow the cooking instructions on the product label. In addition, one of the consumer behavior research studies discussed above found that nearly a quarter of the study participants were unaware that the NRTE frozen chicken product they prepared was raw, and 38 percent of the participants reported not using their food thermometer at home to check that NRTE breaded stuffed chicken products were properly cooked. The other study found that 54 percent of participants reported that they prepared NRTE breaded stuffed chicken products using appliances other than or in addition to ovens, even though the labeling of NRTE breaded stuffed chicken products typically states that the product should only be cooked in a conventional oven.

Information from outbreak investigations also found that some case patients reported following the cooking instructions on the label but still became ill. The characteristics and composition of NRTE breaded stuffed chicken products may have contributed to these illnesses. As noted above, NRTE breaded stuffed chicken products are typically cooked from a frozen state, which increases the risk that

they will not reach an internal temperature needed to destroy *Salmonella* that may be in the product. In addition, because these products contain multiple ingredients that may cook at different rates, consumers may face challenges in determining an accurate internal temperature of these products even when they use a thermometer as recommended on the product label. These findings suggest that NRTE breaded stuffed chicken products present a serious public health risk, regardless of the information provided on the label.

Thus, because measures that have primarily focused on product labeling and consumer handling practices have not been effective in addressing the public health risk associated with *Salmonella* contaminated NRTE breaded stuffed chicken products, the Agency has decided to re-evaluate the status of *Salmonella* in these products under the PPIA.

Salmonella as an "Added Substance" in NRTE Breaded Stuffed Chicken Products

As noted above, a meat or poultry product is adulterated if, among other circumstances, "it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance, such article shall not be considered adulterated … if the quantity of such substance in or on such article does not ordinarily render it injurious to health" (21 U.S.C. 601(m)(1); 21 U.S.C. 453(g)(1)). As stated in its response to the 2020 petition submitted by Marler Clark, LLP, FSIS has traditionally viewed *Salmonella* as "naturally occurring" in food animals. However, the Agency also stated that it was reassessing this interpretation as part of its *Salmonella* in poultry initiative and considering whether *Salmonella* should be considered an adulterant in any poultry products under any of the PPIA's adulteration definitions. As discussed below, FSIS has reassessed whether *Salmonella* should be considered as a "naturally occurring" substance in NRTE breaded stuffed chicken products. Based on this assessment, the Agency has tentatively concluded that for these specific products, *Salmonella* is an added substance within the meaning of 21 U.S.C. 453(g)(1) of the PPIA. This tentative determination is limited to *Salmonella* in NRTE breaded stuffed chicken products. FSIS will

reassess its traditional view of *Salmonella* as "naturally occurring" in other poultry products in the near future as it develops a new strategy to control *Salmonella* in poultry products.[74]

Salmonella is present in the gastrointestinal tract of live birds, and there is evidence that extraintestinal *Salmonella* exist in poultry skin, livers, bones, and bone marrow before processing.[75] Salmonella is not, however, ordinarily found in the muscle tissue of healthy birds. NRTE breaded stuffed chicken products contain raw, comminuted chicken breast meat, trim, or whole chicken breast meat (i.e., further processed chicken parts or comminuted chicken). FSIS sampling data show that further processed chicken parts (breasts, legs, and wings) and comminuted chicken have a higher incidence of *Salmonella* compared to carcasses.[76] This difference is most likely because of cross contamination between positive and negative parts and carcasses during further processing.[77,78]

Further processing presents various opportunities in which *Salmonella* that is present in certain parts of the bird may be added to interior edible muscle where *Salmonella* is not ordinarily found. For example, *Salmonella* can be found in feather follicles in the skin.[79, 80] When the skin is cut, *Salmonella* can be exposed and spread during processing to previously uncontaminated product.[81] Additionally, many NRTE breaded stuffed chicken products are made with comminuted chicken. Comminuted products are those that are ground, mechanically separated, or hand- or mechanically deboned and

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[74] United States Department of Agriculture. (October 19, 2021). USDA Launches New Effort to Reduce *Salmonella* Illness Linked to Poultry. https://www.usda.gov/media/press-releases/2021/10/19/usda-launches-new-effort-reduce-salmonella-illnesses-linked-poultry. *see also* Food Safety and Inspection Service. (December 2, 2021). Pilot Projects: *Salmonella* Control Strategies. https://www.fsis.usda.gov/inspection/inspection-programs/inspection-poultry-products/reducing-salmonella-poultry/pilot

[75] Rimet, C.S., et al. (2019). Salmonella Harborage Sites in Infected Poultry That May Contribute to Contamination of Ground Meat. Frontiers in Sustainable Food Systems 3(2). see also Jones-Ibarra, A. M., et al. (2019). Salmonella recovery from chicken bone marrow and cecal counts differ by pathogen challenge method. Poult Sci 98(9): 4104-4112. see also Cox, N. A., et al. (2007). Recovery of Campylobacter and Salmonella Serovars From the Spleen, Liver and Gallbladder, and Ceca of Six-and Eight-Week-Old Commercial Broilers. Journal of Applied Poultry Research 16(4): 477-480.

[76] Sampling Results for FSIS-Regulated Products. Available at: https://www.fsis.usda.gov/science-data/sampling-program/sampling-results-fsis-regulated-products

[77] FSIS Guidance for Controlling Salmonella in Poultry (June 2021) p. 59. Available at: https://www.fsis.usda.gov/sites/default/files/media_file/2021-07/FSIS-GD-2021-0005.pdf

[78]Codex Guideline for the Control of Campylobacter and Salmonella in Chicken Meat at: https://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FStandards%252FCXG%2B78-2011%252FCXG_078e.pdf

[79] Kim J-W and Slavik MF. 1996. Cetylpyridinium Chloride (CPC) treatment on poultry skin to reduce attached *Salmonella*. J. Food Prot. 59: 322-326.

[80] Wu D, Alali WQ, Harrison MA, and Hofacre CL. 2014. Prevalence of Salmonella in neck skin and bone of chickens. J Food Prot. 77(7): 1193-1197.

[81] FSIS Guidance for Controlling Salmonella in Poultry (June 2021) pp. 59-60. Available at: https://www.fsis.usda.gov/guidelines/2021-0005

further chopped, flaked, minced, or otherwise processed to reduce particle size. Because of the nature of comminuted processes, *Salmonella* contamination in chicken skin and bone can spread throughout an entire batch or lot through cross contamination. FSIS sampling data show that ground and other raw comminuted chicken products that were produced using either bone-in or skin-on source materials were more likely to be contaminated with *Salmonella* than those fabricated from deboned, skinless source materials.[82] In addition, *Salmonella*-negative raw poultry parts and comminuted poultry may become cross-contaminated by contact with *Salmonella*-contaminated equipment or when they are commingled with *Salmonella*-positive products, such as when they are collected in combo bins for further processing.[83,84] *Salmonella*-contaminated equipment used to incorporate the stuffed ingredients into the chicken component of NRTE breaded stuffed chicken products may also contribute to *Salmonella* contamination in these products. Thus, because *Salmonella* may be added to previously uncontaminated chicken parts and comminuted chicken during processing, and because the chicken component of NRTE breaded stuffed chicken products is made from further processed poultry parts or comminuted poultry, FSIS has tentatively concluded that *Salmonella* is an "added substance" when present in these specific products.

The Adulteration Standard for *NRTE Breaded Stuffed Chicken Products*

As noted above, a poultry product that bears or contains any added poisonous or deleterious substance which may render it injurious to health or that bears or contains an inherent substance in sufficient quantity to ordinarily render it injurious to health is adulterated under the PPIA (21 U.S.C. 453(g)(1)). A poultry product can also be found to be adulterated if it is "unsound, unhealthful, unwholesome, or otherwise unfit for human food" (21 U.S.C. 453(g)(3)).

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[82] FSIS Guidance for Controlling Salmonella in Poultry (June 2021) pp. 65-66, Table 4 FSIS exploratory sampling test results, raw comminuted chicken by source material composition (6/1/13-6/30/15, 2,688 samples. Available at: https://www.fsis.usda.gov/guidelines/2021-0005

[83] FSIS Guidance for Controlling *Salmonella* in Poultry (June 2021) pp. 59. Available at: https://www.fsis.usda.gov/guidelines/2021-0005

[84] Codex Guideline for the Control of Campylobacter and Salmonella in Chicken Meat at https://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FStandards%252FCXG%2B78-2011%252FCXG_078e.pdf

Consistent with its approach used to determine the status of certain STEC in raw non-intact beef products and intact cuts to be further processed into non-intact products, to assess the status of *Salmonella* in NRTE breaded stuffed chicken products under the PPIA, FSIS has evaluated the available information on *Salmonella* serotypes associated with human illnesses, the *Salmonella* infectious dose, the severity of human illnesses caused by *Salmonella*, and consumer preparation practices associated with NRTE breaded stuffed chicken products as documented in outbreak investigations associated with these products and as described in the consumer behavior research studies discussed above. Based on this evaluation, FSIS is proposing to declare that NRTE breaded stuffed chicken products contaminated with *Salmonella* at levels of 1 CFU/gram or higher are adulterated within the meaning of 21 U.S.C. 453(g)(1) and 21 U.S.C. 453(g)(3) of the PPIA.

Because FSIS has tentatively concluded that *Salmonella* is an added substance in NRTE breaded stuffed chicken products, the Agency has tentatively concluded that these products are adulterated when they contain *Salmonella* at levels of 1 CFU per gram or higher because *Salmonella* at these levels "may render" NRTE breaded stuffed chicken products injurious to health (21 U.S.C. 453(g)(1)).[85] Moreover, FSIS is proposing to declare that NRTE breaded stuffed chicken products that are contaminated with *Salmonella* at levels of 1 CFU per gram or above are adulterated within the meaning of 21 U.S.C. 453(g)(3) because when they contain *Salmonella* at these levels, NRTE breaded stuffed chicken products present a sufficiently serious risk of causing human *Salmonella* illnesses such as to make them unhealthful, unwholesome, or otherwise unfit for human food. The basis for this proposed determination is discussed below.

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[85] The adulteration definition in 21 U.S.C. 453(g)(1) includes two separate standards for determining whether a product is adulterated. Under 21 U.S.C. 453(g)(1), if a substance is an "added substance" the product is adulterated if the substance "may render" the product injurious to health. If the substance is not added, the product is adulterated "if the quantity of such substance in or on" the product "ordinarily" renders it injurious to health. As discussed in this document, FSIS has tentatively concluded that when present in NRTE breaded stuffed chicken products, *Salmonella* at 1 CFU per gram or higher meets the definition of an "added substance" that "may render" these products injurious to health. Although the "may render" standard is the primary basis for FSIS' tentative determination that the product is adulterated, FSIS also believes that NRTE breaded stuffed chicken products that contain *Salmonella* at 1 CFU per gram or higher meet the more stringent "ordinarily injurious" standard for substances that are not added because ordinary consumer handling and preparation, as reported in outbreak investigations and consumer research, may not reduce *Salmonella* to levels that do not result in illness and may also contribute to cross-contamination when these products are prepared in the home.

Pathogen serogroups or types associated with human illness. With respect to specific *Salmonella* serotypes, the *Salmonella* outbreaks associated with NRTE breaded stuffed chicken products investigated by FSIS and public health partners have been associated with the serotypes Typhimurium, Heidelberg, I 4,[5],12:i:-, and Enteritidis and tend to reflect the outbreak serotypes for raw chicken products in general. All outbreaks documented after 2009 have involved *Salmonella* Enteritidis. Additionally, from 2017 to 2021, FSIS and public health partners investigated 13 *Salmonella* outbreaks potentially associated with all raw chicken products.[86] Serotypes Typhimurium, Enteritidis, Blockley, and Infantis account for 92 percent of the outbreak related illnesses. These 4 serotypes account for 77.4 percent of 1,946 illnesses reported in the National Outbreak Reporting System due to *Salmonella* from chicken during the years 2015-2019 (61 outbreaks).[87] Approximately 2,500 *Salmonella* serotypes have been identified[88], though not all serotypes have been isolated from chicken. Almost all strains of *Salmonella* are pathogenic as they have the ability to invade, replicate and survive in human host cells, resulting in potentially fatal disease[89], though not all are equally likely to cause illness. Additionally, according to the CDC, reported cases from outbreaks only represent a fraction of actual cases.[90] Thus, because the reported outbreaks represent a small portion of *Salmonella* illnesses, the serotypes that have been found to be associated with *Salmonella* outbreaks do not capture all serotypes that are causing illnesses.

Consistent with its approach used to determine the adulterant status of STEC, FSIS considered declaring the *Salmonella* serotypes responsible for the largest proportion of *Salmonella* illness outbreaks associated with chicken as adulterants in NRTE breaded stuffed chicken products. As the pathogens and

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[86] FSIS Outbreak Reports at: https://www.fsis.usda.gov/food-safety/foodborne-illness-and-disease/outbreaks.

[87] Centers for Disease Control and Prevention: National Outbreak Reporting System at: https://wwwn.cdc.gov/norsdashboard/.

[88]Brenner FW, Villar RG, Angulo FJ, Tauxe R, Swaminathan B. Salmonella nomenclature. J Clin Microbiol. 2000 Jul;38(7):2465-7. doi: 10.1128/JCM.38.7.2465-2467.2000. PMID: 10878026; PMCID: PMC86943.

[89] Shu-Kee Eng, Priyia Pusparajah, Nurul-Syakima Ab Mutalib, Hooi-Leng Ser, Kok-Gan Chan & Learn-Han Lee (2015) *Salmonella*: A review on pathogenesis, epidemiology and antibiotic resistance, Frontiers in Life Science, 8:3, 284-293, DOI: 10.1080/21553769.2015.1051243

[90] Scallan, E., Hoekstra, R. M., Angulo, F. J., Tauxe, R. V., Widdowson, M., Roy, S. L. Griffin, P. M. (2011). Foodborne Illness Acquired in the United States—Major Pathogens. Emerging Infectious Diseases, 17(1), 7-15. https://doi.org/10.3201/eid1701.p11101; Mead, P.S., et al., Food-related illnesses and deaths in the United States. *Emerging Infect Dis,* Oct1999. 5(5) p. 607-625.

products are different, there were different considerations when making this determination. First, *Salmonella* virulence factors are not as well understood as those of STEC. With *Salmonella,* higher virulence is associated with enhanced ability to survive and grow in the gut or to attach to and invade human cells, which is driven by changes to several mechanisms, including mobile genetic elements and resident genes as well as variations in gene sequence and expression. In an August 2018 report, the NACMCF was unable to find evidence in the literature for any determinant that correlated with high virulence in human foodborne disease.[91] The NACMCF noted that a few *Salmonella* serotypes are consistently associated with the greatest incidence of human disease. However, this disparity among serotypes may be related to survival in animal hosts or during food harvesting and processing rather than serotype-specific differences in human virulence.

FSIS seeks to better understand *Salmonella* characteristics, including virulence, and actively engages in and encourages research in this area. In October 2021, FSIS launched a new effort aimed at developing a stronger and more comprehensive framework for reducing *Salmonella* illnesses associated with poultry products.[92] As part of this initiative, FSIS will leverage USDA's strong research[93] capabilities and strengthen its partnership with the USDA Research Education and Economics[94] mission area to address data gaps and develop new laboratory methods to guide future *Salmonella* policy. FSIS is also exploring more efficient methods to enumerate pathogens in samples, detect virulence factors in pathogens, and investigate new pathogen characterization methods. As science and laboratory technologies advance, FSIS will continue to use the most innovative and sensitive methods available to protect public health.

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[91] NACMCF (2019). Response to Questions Posed by the Food Safety and Inspection Service Regarding *Salmonella* Control Strategies in Poultry. *Journal of Food Protection* 82(4): 645-668.

[92] USDA Launches New Effort to Reduce *Salmonella* Linked to Poultry (October 19, 2021) at: https://www.usda.gov/media/press-releases/2021/10/19/usda-launches-new-effort-reduce-salmonella-illnesses-linked-poultry

[93] FSIS Food Safety Research Priorities and Studies, available at https://www.fsis.usda.gov/science-data/research-priorities#:~:text=FSIS%20Data%20Gaps%20%20%20%20Study%20Title,may%20survi%20...%20%209%20more%20rows%20?msclkid=f7030eaea6c411ec9e91f63d1dde98ff

[94] USDA Research, Education, and Economics website, available at: https://www.ree.usda.gov/#:~:text=The%20Research%2C%20Education%2C%20and%20Economics%20%28REE%29%20mission%20area,and%20youth%20through%20integrated%20research%2C%20analysis%2C%20and%20education.?msclkid=261bd671a6c411eca6c1c87daaae90cd

Therefore, after considering the current state of the science and laboratory technology, to address the significant public health risk associated with NRTE breaded stuffed chicken products contaminated with *Salmonella*, FSIS is proposing to declare, at certain levels, all *Salmonella* as adulterants in NRTE breaded stuffed chicken products at this time. Although certain *Salmonella* serotypes have been associated with illnesses identified in outbreak investigations associated with NRTE breaded stuffed chicken products, as discussed above, the basis for *Salmonella* virulence is not fully understood, all *Salmonella* serotypes have the potential to cause illness, and, as noted in the 2018 NACMCF report, the disparity among serotypes may be related to factors other than serotype-specific differences in human virulence. In addition, FSIS' current laboratory methods typically require approximately 14 days from sample collection for results to be reported for *Salmonella* serotypes. Therefore, FSIS is tentatively declaring all *Salmonella* at certain levels as an adulterant in NRTE breaded stuffed chicken products. As noted above, FSIS is actively seeking research to address data gaps and develop more efficient laboratory methods to, among other things, enumerate and characterize pathogens and detect virulence factors in pathogens. FSIS will continue to evaluate and, if necessary, refine its proposed determination on the status of *Salmonella* as an adulterant in NRTE breaded stuffed chicken products as advances in science and technology related to pathogen levels, serotypes, and infectious dose become available. FSIS will consider public comments before issuing a final determination of *Salmonella* as an adulterant in NRTE breaded stuff chicken products.

Infectious dose. Foodborne outbreaks are extraordinary events where conditions combine to result in illness among a group of people. It could be that a highly sensitive group of people, e.g., immunosuppressed, consumed contaminated product. It could be that a unique and significantly virulent strain is present in the food. It could be the result of a process failure where a high number of infectious organisms are present in the food. Outbreaks also may occur due to exposure of a large number of consumers to contaminated product. A combination of those four factors – agent virulence, dose, consumer susceptibility, and the extent of exposure - elevates the potential for foodborne outbreaks.

In assessing the status of certain STEC as adulterants in non-intact raw beef products and intact cuts to be further processed into non-intact products, FSIS considered data that indicates that the infectious dose for these specific serogroups is relatively low. Although *Salmonella* data are limited, international and domestic outbreak investigations associated with a variety of food products have been used to estimate the relationship between the number of organisms consumed and the probability of illness. Five *Salmonella* foodborne outbreaks have shown that *Salmonella* can cause illness from exposure of 10 or fewer organisms per person.[95] Additionally, several outbreaks from a range of *Salmonella* serotypes in various food products have shown that exposure from 11 to 420 organisms per person can result in illness.[96] Thus, in these published studies, the infectious dose ranged from 1 to 420 *Salmonella* organisms per person. Using a dose-response model approach utilizing outbreak data, and accounting for variation among outbreaks represented by the data (predominately Enteritidis and Typhimurium serotypes), the average *Salmonella* median illness dose was 36 colony forming units (CFU) (with 95% prediction interval of 0.69–1.26×10^7 CFU).[97] The median illness dose refers to the dose at which 50% of individuals in an exposed population will experience symptomatic illness. The average median illness dose and its prediction interval reflect variability among outbreak strains and exposed

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[95] Killalea, D., et al., International Epidemiological and Microbiological Study of Outbreak of Salmonella Agona Infection from a Ready to Eat Savoury Snack—I: England and Wales and the United States. 1996, British Medical Journal Publishing Group.; Shohat, T., et al., International Epidemiological and Microbiological Study of Outbreak of Salmonella Agona Infection from a Ready to Eat Savoury Snack—Ii: Israel. BMJ, 1996. 313(7065): p. 1107-1109.; D'aoust, J.Y. and J.Y.D. Aoust, Infective Dose of Salmonella Typhimurium in Cheddar Cheese. American Journal of Epidemiology, 1985. 122(4): p. 717-720.; D'aoust, J.Y., D.W. Warburton, and A.M. Sewell, Salmonella Typhimurium Phage-Type 10 from Cheddar Cheese Implicated in a Major Canadian Foodborne Outbreak. Journal of Food Protection, 1985. 48(12): p. 1062-1066.; Kapperud, G., et al., Outbreak of Salmonella Typhimurium Infection Traced to Contaminated Chocolate and Caused by a Strain Lacking the 60-Megadalton Virulence Plasmid. J Clin Microbiol, 1990. 28(12): p. 2597-601.; Hockin, J. C. et al., An International Outbreak of Salmonella Nima from Imported Chocolate. J Food Prot. 1989. 52(1): p. 51-54.; Lehmacher, A., Bockemuhl, J., and Aleksic. S. Nationwide outbreak of human salmonellosis in Germany due to contaminated paprika and paprika-powdered potato chips. 1995. Epidemiol Infect. 115: p. 501-11.

[96] Kasuga F.et al., Archiving of food samples from restaurants and caterers - Quantitative profiling of outbreaks of foodborne salmonella in Japan. Journal of Food Protection, 2004. 67: p. 2024-2032; Blaser, M. J., and Newman, L. S. A review of human salmonellosis: I. Infective dose. Rev Infect Dis., 1982.4: p.1096-106; Abe, K., N. et al., Prolonged incubation period of Salmonellosis associated with low bacterial doses. Journal of food protection, 2004. 67: p. 2735-2740; Hara-Kudo, Y. and K. Takatori, Contamination level and ingestion dose of foodborne pathogens associated with infections. Epidemiology and Infection, 2011. 139: p. 1505-1510; Hennessy T. W., et al., A national outbreak of Salmonella enteritidis infections from ice cream. N Engl J Med, 1996. 334(20): p. 1281-6; Hedberg C. W., et al., A multistate outbreak of Salmonella javiana and Salmonella oranienburg infections due to consumption of contaminated cheese. *JAMA*, 1992. 268(22): p. 3203-7; Todd, E. C., et al., Outbreaks where food workers have been implicated in the spread of foodborne disease. Part 4. Infective doses and pathogen carriage. *J Food Prot*, 2004. 71: p. 2339-73; Scheil W., et al., A South Australian Mdbandaka outbreak investigation using a database to select controls. *Aust NZ J Public Health*, 1998. 22(5): p. 536-9; Tamber, S., E. Swist, and D. Oudit, Physicochemical and bacteriological characteristics of organic sprouted chia and flax seed powders implicated in a foodborne Salmonellosis outbreak. *Journal of Food Protection*, 2016. 79(5): p. 703-709.

[97] Teunis P.F., et al., Dose-response modeling of Salmonella using outbreak data. *Int J Food Microbiol*, 2010. 144(2): p. 243-9.

populations and uncertainty about the dose-response relationship. A similar dose-response approach was developed by the World Health Organization Food and Agriculture Organization of the United Nations for risk assessments for *Salmonella* in eggs and broiler chickens.[98] Also using outbreaks, the model estimated a 13 percent chance of becoming ill if ingesting 100 organisms. Even at the level of 1 organism ingested, there was still a non-zero chance of illness (0.25 percent). These *Salmonella* outbreaks as well as dose-response modeling of *Salmonella* outbreaks, suggest that exposure to a small number of *Salmonella* organisms can result in foodborne illness. Assuming a minimum of 0.5 log (68%) *Salmonella* reduction likely achieved with even partial cooking, the proposed level of 1 CFU per gram (assuming a typical 70-88 gram portion size) should significantly mitigate the risk of illness associated with NRTE breaded stuffed chicken products.

Taking into account: 1) the range of infectious doses referenced above (between 1-420 CFU), in particular that a *Salmonella* dose-response model based on outbreaks showed the average *Salmonella* median illness dose was 36 CFU; 2) that most consumers will cook NRTE breaded stuffed chicken products to some degree, resulting in mitigation of the exposure to the pathogen; 3) that the average chicken portion in a NRTE breaded stuffed chicken product is approximately 70-88 grams[99]; and 4) that, at this point, technology does not exist to identify serotype pathogenicity factors in a timely manner, FSIS has tentatively concluded that *Salmonella,* at a concentration lower than 1 CFU per gram, would not ordinarily render this type of NRTE commodity injurious to health or make them unwholesome, unhealthful or otherwise unfit for human food. The Agency believes that this target is also achievable under industry production conditions and that laboratory analytical methodology is available to detect organisms at this level. FSIS requests comments on this tentative conclusion and whether there are studies that support an alternative adulteration threshold.

Severity of illnesses. When FSIS declared certain STEC as adulterants in raw non-intact beef products and intact cuts to be further processed into non-intact beef products, the Agency considered the severity of the consequences of an infection with these pathogens and noted that they had been

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[98] World Health Organization, Risk assessment of Salmonella in eggs and broiler chickens, March 25, 2002. Available at: https://www.who.int/publications/i/item/9291562293

[99] Based on product formulation information.

linked with serious, life-threatening human illnesses, such as hemorrhagic colitis and HUS. Although the symptoms of *Salmonella* infections are typically not reported to be as severe as those associated with STEC, *Salmonella* can cause bloody diarrhea, fever, abdominal cramps, nausea, and vomiting. In some instances, *Salmonella* enters the blood and makes its way to other areas of the body including, but not limited to, the heart, lung, bone, joints and the central nervous system.[100] This can result in severe illness requiring hospitalizations and even death, especially in vulnerable populations, such as very young, elderly, and immunocompromised individuals. Even when *Salmonella* is no longer detectable in the body, prior *Salmonella* illness has also been associated with an increased risk in colon cancer.[101] And can cause debilitating, long-lasting conditions including inflammatory bowel disease, irritable bowel syndrome and reactive arthritis.

Furthermore, a study that allows for a comparison of case-fatality proportions of both *Salmonella* and STEC O157 demonstrates a higher frequency of deaths among *Salmonella* cases than among STEC O157 cases.[102] The estimated annual domestic foodborne illnesses reported in the study were 1,027,561 and 63,153 for *Salmonella* and STEC O157, respectively. Annual deaths from domestic foodborne illnesses are 378 and 20 for *Salmonella* and STEC O157, respectively. Therefore, *Salmonella* deaths occur at a frequency of 4 per 10,000 illnesses, while STEC O157 deaths occur at a frequency of 3 per 10,000 illnesses.

When FSIS declared certain STEC as adulterants in raw non-intact beef products and intact cuts to be further processed into non-intact products, there was a limited history of documented illnesses and outbreaks associated with these serogroups in raw beef. In fact, when FSIS declared the six non-O157:H7 STEC as adulterants, the Agency noted that the illnesses associated with these strains had not primarily been due to contamination in beef (76 FR 58158). However, because these pathogens had been associated with severe, debilitating illnesses, particularly in vulnerable populations, FSIS

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[100] Batz, M.B., et al., Long-Term consequences of foodborne illness. *Infect Dis Clin North Am*, Sept 2013. 28(3) p. 599-661; Hohmann, E. L., Nontyphoidal Salmonellosis, *Clin Infect Dis*, Sept 2001. 32 p. 263-269; Heymann, D. Salmonellosis. Control of Communicable Disease Manual, 2021.

[101] Mughini-Gras, L. et al. Increased colon cancer risk after severe *Salmonella* infection. *PLoS ONE*, 2018. 13(1): p. 1-19. https://doi.org/10.1371/journal.pone.0189721.

[102] Scallan, et al., 2011.

determined that, in order to protect public health, it was necessary to evaluate their status as adulterants in certain raw beef products under the FMIA.

In contrast, there has been a long history of documented *Salmonella* illness outbreaks associated with NRTE breaded stuffed chicken products produced by different establishments that included illnesses that required hospitalization. The most recent multi-state outbreak in 2021 included 36 cases from 11 states, and of 32 people with information available, 12 were hospitalized. The actual number of cases and hospitalizations are likely higher because the overwhelming number of *Salmonella* illnesses are not diagnosed and reported to public health officials.[103]

In addition, because NRTE breaded stuffed chicken products are typically stored in the freezer and consumed over time, *Salmonella* illness outbreaks associated with these products tend to persist for several months, even when implicated products represent a few days of production. Thus, the long, recurring history and ongoing nature of *Salmonella* illness outbreaks associated with NRTE breaded stuffed chicken products raise significant concerns about the impact on human health of *Salmonella* contamination in these products.

Consumer cooking practices. In addition to their relatively low infectious dose and potential to cause severe illness, certain STEC are considered as adulterants in raw non-intact beef product because there is evidence to show that these strains can survive what many consumers consider to be proper cooking of these products. Information from the outbreak investigations associated with NRTE breaded stuffed chicken products and the 2020 consumer behavior research report show that with respect to consumer preparation practices, *Salmonella* in NRTE breaded stuffed chicken products presents similar issues to STEC-contaminated raw ground beef because both products are frequently consumed after preparation that may not destroy pathogens in the product.

As noted earlier, NRTE breaded stuffed chicken products contain raw, comminuted chicken breast meat or whole chicken breast meat, but the finished product is heat-treated only to set the batter or breading on the exterior of the product, which is not sufficient to destroy *Salmonella* that may

[103] Scallan, et al. 2011; Mead, P.S., et al., Food-related illnesses and deaths in the United States. *Emerging Infect Dis,* Oct1999. 5(5) p. 607-625.

be present in the product but may impart an RTE appearance to the consumer. Information from *Salmonella* illness outbreak investigations associated with NRTE stuffed chicken products show that, even with labeling that prominently discloses that these products are raw, the fact that they may appear fully cooked and are typically prepared from a frozen state may lead some consumers to believe that the products are properly cooked when reheated for aesthetic or palatability purposes rather than to a temperature sufficient to kill pathogenic bacteria as instructed on the product labeling. On the other hand, information from some earlier *Salmonella* outbreak investigations associated with NRTE breaded stuffed chicken product found that some cases that became ill reported following the validated cooking instructions on the product label. Thus, information from outbreak investigations also shows that the ordinary consumer cooking practices for NRTE breaded stuffed chicken products may not be sufficient to destroy *Salmonella* that may be present in the product regardless of the information provided on the product label.

Also, as discussed above, FSIS consumer research on preparation of NRTE breaded stuffed chicken product found that despite reading the product label, 22 percent of participants were unaware that the NRTE breaded stuffed chicken product they prepared was raw, and 11 percent incorrectly believed that the product was fully cooked. The study also found that while 99 percent of the participants self-reported that they had read the manufacturer's instructions for the NRTE breaded stuffed chicken products, which instructed consumers to use a food thermometer to check that the product reached an internal temperature of 165°F, only 77 percent of a control group used a thermometer. With respect to handwashing, the study found that during preparation of NRTE breaded stuffed chicken products, handwashing was attempted only 5 percent of the time it was required, e.g., after touching the NRTE breaded stuffed chicken product. The study concluded that this was most likely because the participants were preparing a NRTE frozen breaded product rather than fresh poultry. Thus, these findings show that ordinary consumer handling of NRTE breaded stuffed chicken product may contribute to cross contamination, which may be why some outbreak cases that reported following validated cooking instructions still became ill.

In addition, the 2022 study on appliances used to prepare NRTE breaded stuffed chicken products discussed above found that although the labeling of NRTE breaded stuffed chicken products typically includes instructions to cook the product in an oven, 54 percent of study respondents reported preparing these products using appliances other than or in addition to ovens.

Proposed determination. After careful consideration of the information presented above, FSIS has tentatively determined that NRTE breaded stuffed chicken products contaminated with *Salmonella* present a significant public health concern because data from outbreak investigations as well as consumer behavior research studies show that common consumer preparation practices associated with these products may not destroy organisms that may be present in the product. Information from consumer behavior research also shows that common consumer handling of NRTE breaded stuffed chicken products may also contribute to cross contamination. As discussed above, *Salmonella* has been associated with severe and debilitating human illness and available data suggest that the *Salmonella* infectious dose is relatively low. In addition, because NRTE breaded stuffed chicken products have been associated with several *Salmonella* illness outbreaks, and because of the recurring nature of these outbreaks, FSIS has tentatively determined that the status, under the PPIA, of NRTE breaded stuffed chicken products contaminated with *Salmonella* must depend on whether there is adequate assurance that subsequent handling of the product will result in a product that does not contain *Salmonella* at levels sufficient to cause human illness when consumed (64 FR 2803). Information from *Salmonella* illness outbreaks associated with NRTE breaded stuffed chicken products and the information on consumer handling practices with respect to these products show that labeling that informs consumers that these products are raw and how to prepare them safely fails to provide such assurance. Thus, because *Salmonella* can survive ordinary handling and cooking practices for NRTE breaded stuffed chicken products, FSIS has tentatively concluded that the appropriate response to protect public health is to ensure that products contaminated with *Salmonella* at levels sufficient to cause human illness are excluded from commerce.

Therefore, for the reasons discussed above, FSIS is proposing to declare that NRTE breaded stuffed chicken products contaminated with *Salmonella* at levels of 1 CFU/gram or higher are

adulterated as defined in 21 U.S.C. 453(g)(1)) and 21 U.S.C 453(g)(3)) of the PPIA. FSIS requests comments on this proposed determination and whether there are alternative bases for determining adulteration of these NRTE products.

IV. Proposed Policy Implementation

HACCP Reassessment

The HACCP system regulations require that every establishment reassess the adequacy of its HACCP plan at least annually and whenever any changes occur that could affect the underlying hazard analysis or alter the HACCP plan (9 CFR 417.4(a)(3)). If finalized, FSIS' proposed determination that *Salmonella* at levels of 1 CFU/gram or higher is an adulterant in NRTE breaded stuffed chicken products would be such a change. Thus, if FSIS finalizes this proposed determination, all establishments that produce Heat Treated but Not Fully Cooked – Not Shelf Stable NRTE breaded stuffed chicken products would need to reassess their HACCP plans. Establishments that make changes to their production process as a result of their reassessment would also need to re-validate their HACCP plans. FSIS would issue instructions to inspection program personnel in establishments that produce NRTE breaded stuffed chicken products to verify that these establishments have completed their reassessment before the effective date of any final determination resulting from this proposal.

Proposed Implementation and Status of Laboratory Methods

As noted above, FSIS is proposing a routine sampling and verification testing program for *Salmonella* in NRTE breaded stuffed chicken products in which the Agency would collect and analyze samples from the chicken component prior to breading and stuffing, for *Salmonella* at 1 CFU per gram or higher. FSIS would collect the verification samples after the establishment has completed all processes needed to prepare the chicken component to be stuffed and breaded to produce a final NRTE breaded stuffed chicken product. Should FSIS finalize this proposed testing program, the Agency would consider NRTE breaded stuffed chicken products produced with a chicken component that tested positive for *Salmonella* at levels of 1CFU per gram or higher to be adulterated. FSIS would sample the chicken component prior to stuffing and breading and would perform, evaluate, determine, and report whole

genome sequencing (WGS), serotype, levels, and antimicrobial resistance (AMR) profile for each *Salmonella* isolate identified in the sampling program.[104]

If FSIS finalizes this proposed sampling plan, data gathered from the sampling plan would enable the Agency to more precisely gauge the level of hazard posed by *Salmonella* in the chicken component of these products prior to stuffing and breading. As noted above, FSIS intends to further evaluate and, if necessary, refine the proposed status of *Salmonella* as an adulterant in NRTE breaded stuffed chicken products as advances in science and technology related to pathogen levels, serotypes, and virulence genes become available.

The detection and isolation methodology for *Salmonella* is described in MLG chapter 4.13, of the FSIS Microbiology Laboratory Guidebook.[105] When sampling the chicken component of NRTE breaded stuffed chicken products under this proposed determination**,** FSIS would collect one pound of the chicken component prior to stuffing and breading from the establishment to analyze 325 grams per test for *Salmonella***.** Samples would be initially screened, post-enrichment, for the presence or absence of *Salmonella*. Samples that screen negative would be reported as "negative." For samples that screen positive, FSIS would use selective and differential culture-based media and proteomics testing to identify the presumptive positive samples. All presumed positive samples would be subject to confirmatory tests and enumeration. A sample is considered confirmed positive for *Salmonella* after completion of both cultural and confirmatory tests. Any chicken component "confirmed positive" with *Salmonella* levels of 1 CFU per gram or higher prior to stuffing and breading would need to be diverted to a use other than NRTE breaded stuffed chicken products. Any NRTE breaded stuffed chicken products that contain a chicken component confirmed positive with *Salmonella* levels of 1 CFU per gram or higher prior to stuffing and breading would be considered adulterated.

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[104] This information would be reported as with any test result. Inspectors would get result through PHIS. FSIS would report out through Laboratory Information Management System (LIMS) Direct for industry as well as the result would be in the new PHIS sample result history report. The results would also be in public release data sets that the agency does quarterly. The WGS data would also be uploaded to NCBI as are other Salmonella isolates.

[105] FSIS Microbiology Laboratory Guidebook available at: https://www.fsis.usda.gov/news-events/publications/microbiology-laboratory-guidebook

FSIS estimates that negative results would routinely be available within 48 hours of shipment of the samples to the laboratory, assuming overnight sample transit coupled with a 24-hour sample enrichment and screening at the laboratory. For samples that screen positive, an additional 2 to 4 days may be necessary for a confirmed positive or negative result. Enumeration is run concurrently with confirmatory testing and would be reported with the confirmed positive result. *Salmonella* serotypes, WGS, and AMR profile would require at least 14 days for result reporting. These timeframes and methods may change as FSIS incorporates new laboratory technologies into its sampling verification program.[106]

To help inform FSIS verification sampling plan resulting from this proposal, FSIS conducted a study with the Food Emergency Response Network (FERN) Cooperative Agreement Laboratories to gather data at retail to provide information about the positive rate of *Salmonella* in NRTE breaded stuffed chicken products. Through the FERN, FSIS has cooperative agreements with 11 geographically dispersed state laboratories that participated in this study: California Department of Public Health Food and Drug Laboratory, Colorado Department of Agriculture, Florida Department of Agriculture, State Hygienic Laboratory of Iowa, Michigan Department of Health and Human Services, Minnesota Department of Agriculture, Missouri Department of Health, New York Department of Health Wadsworth Center, Ohio Department of Agriculture, Texas State Chemist Laboratory, and Virginia Division of Consolidated Laboratory Services. From July 1, 2022, to September 30, 2022, these laboratories purchased locally available, NRTE breaded stuffed chicken products at retail and tested them for the presence of *Salmonella* and sanitary indicator aerobic organism counts using the

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[106] For example, on July 8, 2022, FSIS announced that it had awarded a contract to bioMérieux to incorporate its non-enrichment quantification system for *Salmonella, '*GENE-UP™ QUANT *Salmonella,'* into the Agency's laboratory system. The Agency evaluated commercially available quantification systems and determined that this technology is the most appropriate for use in the high throughput FSIS laboratory environment. FSIS stated that in the future, the Agency would announce when the method is available and when it will be implemented in all three FSIS food testing laboratories. FSIS also stated that it plans to extend pathogen quantification technology to sample types other than raw poultry rinses in the future (see FSIS Constituent Update, Jul 8, 2022, *FSIS to include Salmonella Quantification in Raw Poultry Rinse Samples*. Available at: https://www.fsis.usda.gov/news-events/news-press-releases/constituent-update-july-8-2022#:~:text=Salmonella%20quantification%20is%20a%20significant%20step%20in%20FSIS%E2%80%99,regulatory%20sample%2C%20not%20solely%20its%20presence%20or%20absence.

current validated methods that each state laboratory employed. The laboratories obtained approximately 15 samples per month depending on availability in their local area and retail stores. Fifty-eight of the 487 samples collected were positive for the presence of *Salmonella*. The laboratories that used *Salmonella* detection and sample preparation methods that are the same as FSIS MLG 4.12 found *Salmonella* in 36 (27%) samples. Out of 58 isolates, 18 (31%) were *Salmonella* Enteritidis, 22 (38%) *Salmonella* Infantis, 15 (26%) *Salmonella* Kentucky, and 3 (5%) *Salmonella* Typhimurium (3/58). These serotypes include those serotypes associated with the most recent NRTE breaded stuffed chicken product outbreaks and the most common serotypes associated with outbreak related illnesses for all chicken products.[107,108]

The 27 percent-positive rate for *Salmonella* in NRTE breaded stuffed chicken products detected in retail samples is comparable to the 29 percent positive rate detected in FSIS' sampling of ground chicken.[109] These rates are higher than the *Salmonella*-positive rates for other raw chicken products, which suggests that NRTE breaded stuffed chicken products and ground chicken have a higher risk per serving than other raw chicken products. However, consumer preparation practices are more likely to mitigate the risk associated with ground chicken because, unlike NRTE breaded stuffed chicken products, ground chicken clearly appears raw and is not typically cooked from a frozen state.

Thus, given the number of outbreak investigations associated with NRTE stuffed chicken products and the consumer handling practices identified in both outbreak investigations and consumer behavior research, the disposition of the chicken component of NRTE breaded stuffed chicken products prior to stuffing and breading is an important factor in mitigating the public health risk associated with these products. Therefore, FSIS is proposing a verification sampling program for *Salmonella* in NRTE breaded stuffed chicken products in which the Agency would test the chicken component of these products prior to stuffing and breading and require that chicken component lots that confirm positive for *Salmonella* at 1 CFU per gram or higher be diverted to a use other than NRTE breaded stuffed

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[107] FSIS Outbreak Reports at: https://www.fsis.usda.gov/food-safety/foodborne-illness-and-disease/outbreaks.
[108] Centers for Disease Control and Prevention: National Outbreak Reporting System at: https://wwwn.cdc.gov/norsdashboard/
[109] USDA Food Safety and Inspection Service Annual Sampling Report Fiscal Year 2021: https://www.fsis.usda.gov/sites/default/files/media_file/2022-02/FY2021-Sampling-Summary-Report.pdf

chicken products. Under this proposal, such lots could be diverted for use in a fully cooked poultry product or for use in another raw poultry product, such as ground chicken, in which consumer preparation is more likely to mitigate the risk. FSIS has tentatively concluded that such a program would effectively address the serious public health risk associated with *Salmonella* in NRTE breaded stuffed chicken products while minimizing the potential loss associated with product that is confirmed positive for *Salmonella* at 1 CFU per gram. FSIS requests comments on this proposed verification sampling plan and possible alternative sampling plans. FSIS specifically requests comments on whether the Agency's verification sampling program should collect and analyze samples from the final packaged NRTE breaded stuffed chicken product rather than the chicken component prior to stuffing and breading.

Sampled Lot

When FSIS tests a product sample for adulterants, the Agency withholds its determination as to whether product is not adulterated, and thus eligible to enter commerce, until all test results that bear on the determination have been received (77 FR 73401, Dec 10, 2012). Under this policy, establishments must maintain control of products tested for adulterants to ensure that the products do not enter commerce while waiting for receipt of the test results. Thus, if FSIS finalizes its proposed routine *Salmonella* verification testing program for the chicken component in NRTE breaded stuffed chicken products prior to stuffing and breading, establishments that produce these NRTE products would need to control and maintain the integrity of the sampled chicken component lot pending the availability of test results.

Under any final verification sampling plan, FSIS IPP would give establishments that produce NRTE breaded stuffed chicken product advance notice before they collect a product sample from the chicken component for *Salmonella* to give the establishment enough time to control the sampled lot. The sampled lot is the product represented by the sample collected and analyzed by FSIS. Establishments are responsible for providing a supportable basis for defining the sample lot. For sampling purposes, product lots should be defined such that they are microbiologically independent. Microbiological independence is documented by separation, e.g., physical, temporal, or by sanitation

intervention, that clearly delineates the end of one production lot and the beginning of the next. The microbiological results from one test are independent of prior or later lots. In other words, under this proposed verification plan, if a chicken component sample collected prior to stuffing and breading tests positive for *Salmonella* at a level of 1 CFU per gram or higher, products from other chicken component lots should not be implicated.

Generally, FSIS recommends that establishments develop and implement in-plant sampling plans that define production lots or sub-lots that are microbiologically independent of other production lots or sub-lots. Production lots that are so identified may bear distinctive markings on the shipping cartons. FSIS has issued guidance to help establishments comply with the Agency's policy that does not allow product that FSIS has tested for adulterants to enter commerce until test results become available.[110] In addition to providing guidance on adequate control measures establishments can implement for products tested for adulterants, the document also includes guidance on how establishments can define a product lot in order to determine the amount of product that must be controlled pending test results. If FSIS finalizes its proposed *Salmonella* verification sampling for NRTE breaded stuffed chicken product, FSIS would update the guidance to cover *Salmonella* sampling of the chicken component of NRTE breaded stuffed chicken products before the effective date of the sampling program.

As discussed above, under this proposed verification sampling plan, establishments would be required to control the chicken component product sampled by FSIS and not incorporate it into NRTE breaded stuffed chicken products pending the test results. If test results detect *Salmonella* at a level of 1 CFU per gram or higher and the chicken component has been incorporated into a NRTE breaded stuffed chicken product, FSIS would consider the NRTE breaded stuffed chicken product that contains the chicken component represented by the sampled lots to be adulterated and request that the producing establishment recall any product implicated by the product lot that is in commerce. In addition, FSIS would issue a noncompliance record (NR) and, depending on the circumstances, take other appropriate

[110] FSIS Compliance Guideline: Controlling Meat and Poultry Product Pending FSIS Test Results (2013) at: https://www.fsis.usda.gov/guidelines/2013-0003

enforcement action as authorized in 9 CFR part 500 because the establishment would have produced and shipped adulterated product. Such actions may include immediately suspending inspection or issuing a Notice of Intended Enforcement Action.

State Programs and Foreign Government Programs

States that have their own poultry inspection programs for poultry products produced and transported solely within the State are required to have mandatory ante-mortem and post-mortem inspection, reinspection, and sanitation requirements that are at least equal to those in the Federal Meat Inspection Act (21 U.S.C. 661(a)(1)). Therefore, if FSIS finalizes this proposed determination, these States would need to adopt sampling procedures and testing methods to detect *Salmonella* at 1 CFU/gram or above in the chicken component in NRTE breaded stuffed chicken products that are at least equal to FSIS' procedures and testing methods for State-inspected establishments that produce these products.[111] Any State participating in a Cooperative Interstate Shipment Program would need to adopt FSIS' sampling procedures and testing methods to detect *Salmonella* at 1 CFU/gram or above in NRTE breaded stuffed chicken products in selected establishments that produce these products for shipment in interstate commerce (21 U.S.C. 472). Foreign countries that are eligible to export poultry products to the United States must apply inspection, sanitary, and other standards that are equivalent to those that FSIS applies to those products (21 U.S.C. 620). Thus, if FSIS finalizes this proposed determination, in evaluating a foreign country's poultry products inspection system to determine the country's eligibility to export poultry products to the United States, FSIS would consider whether the sampling procedures and testing methods to detect *Salmonella* at 1 CFU/gram in the chicken component in NRTE breaded stuffed chicken products prior to stuffing and breading the country uses are equivalent to those that FSIS uses.

V. Anticipated Costs and Benefits Associated with This Proposed Determination

FSIS has considered the economic effects of this proposed determination. The full analysis is published on the FSIS website as supporting documentation to this *Federal Register* Notice ([insert link]).

[111] FSIS is not aware of any State-inspected establishments that produce NRTE stuffed chicken products.

FSIS is seeking comment on the information and assumptions used in the cost-benefit analysis. A summary of the analysis follows.

Summary of Estimated Costs and Benefits

If finalized, this proposed determination is expected to impact six domestic establishments and cost industry at least $4.33 million annually, assuming a 7 percent discount rate over a ten-year period.[112] These costs are associated with HACCP plan reassessments, holding sampled chicken components in cold storage awaiting test results, and the costs associated with developing and implementing an establishment-conducted sampling program. To varying degrees, industry may also incur costs associated with their individual responses to this policy. The Agency would incur costs associated with sampling and testing for *Salmonella* and conducting FSAs. However, these costs are likely more than offset by consumer and industry benefits.

The benefit from reduced outbreak-related recalls depends on the number of recalls this proposed determination would prevent annually. With a total estimated annual industry cost of $4.33 million, and the estimated quantified benefit of one prevented outbreak-related recall being $25.85 million, total benefits would exceed total costs if the proposed determination prevents at least 1 outbreak-related recall every 5.96 years ($25.85/$4.33).[113] Although the proposed policy may not prevent every possible *Salmonella*-related outbreak or illness in these products, FSIS believes the benefits of the proposed policy would exceed the costs if the policy contributes to preventing at least 1 outbreak-related recall every 60 months.[114] Between 2006 and 2021 there was one outbreak every 16.4 months average (15 years / 11 outbreaks). Also, according to the CDC, reported cases from outbreaks only represent a fraction of actual cases; therefore, the health benefits associated with this new policy is likely to be higher than estimated in the published CBA.[115]

Potential Impact on Small Businesses

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[112] FSIS used its Public Health Information System (PHIS) data accessed on 07/28/2022.
[113] Numbers may not calculate due to rounding.
[114] Numbers rounded to the nearest month.
[115] Scallan, E., Hoekstra, R. M., Angulo, F. J., Tauxe, R. V., Widdowson, M., Roy, S. L. Griffin, P. M. (2011). Foodborne Illness Acquired in the United States—Major Pathogens. Emerging Infectious Diseases, 17(1), 7-15. https://doi.org/10.3201/eid1701.p11101.

In the CBA, FSIS defines high-volume establishments as establishments that produce at least 1 million pounds of NRTE stuffed chicken products annually and low-volume establishments as establishments that produce less than 1 million pounds annually. Using these categories, three of the six establishments that produce NRTE stuffed chicken products were classified as high-volume, and three establishments as low-volume. All three of the low-volume establishments are HACCP size small or very small.[116] FSIS expects the cost burden of this proposed determination on low-volume establishments would be small. Nearly 90 percent of production at these three low-volume establishments is product other than NRTE stuffed chicken products. These establishments would choose to incur costs based on their own economic rationale.

In addition, if FSIS finalizes this proposed determination, FSIS intends to implement routine testing for *Salmonella* and would allow industry time to implement possible changes to food safety systems. A small business would have this time to prepare for changes, lowering the burden. FSIS also assumes establishments needing monetary assistance to comply with any final determination resulting from this proposal would take advantage of the grants and financial options available to small establishments. More information on these loans and grants can be found on the FSIS website.[117]

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[116] Under the HACCP size definitions, large establishments have 500 or more employees, small establishments have between 10 and 499 employees, and very small establishments have less than 10 employees or less than $2.5 million in annual revenue. 61 FR 38806.

[117] Grants and Financial Options, USDA FSIS https://www.fsis.usda.gov/inspection/apply-grant-inspection/grants-financial-options

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Office of the Assistant Secretary for Civil Rights

1400 Independence Avenue, SW

Washington, D.C. 20250-9410; or

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Paul Kiecker,

Administrator.

Appendix A: *Salmonella* Outbreak Investigations Associated with All Chicken Products 1998-2020

Running Total	Data Source	Year	Poultry Type	Product	Subtype
1	CDC NORS	1998	Chicken	chicken, unspecified	Enteritidis
2	CDC NORS	1998	Chicken	chicken	Enteritidis
3	CDC NORS	1998	Chicken	chicken	Enteritidis
4	CDC NORS	1998	Chicken	chicken, unspecified	Group E1
5	CDC NORS	1998	Chicken	chicken, unspecified	Typhimurium
6	PubMed	1998	Chicken	chicken Kiev	Typhimurium
7	CDC NORS	1999	Chicken	chicken salad	Enteritidis
8	CDC NORS	1999	Chicken	chicken, unspecified	Enteritidis
9	CDC NORS	1999	Chicken	chicken, unspecified; mung bean sprouts	Enteritidis
10	CDC NORS	1999	Chicken	chicken, unspecified	Give
11	CDC NORS	1999	Chicken	chicken, baked	Hadar
12	CDC NORS	1999	Chicken	chicken, unspecified	Hadar
13	CDC NORS	1999	Chicken	chicken, bbq	Heidelberg
14	CDC NORS	1999	Chicken	chicken, unspecified	Javiana
15	CDC NORS	1999	Chicken	chicken, other	Muenchen
16	CDC NORS	1999	Chicken	burrito, chicken; taco, chicken; chicken, nuggets/fingers	Typhimurium
17	CDC NORS	1999	Chicken	deli meat, sliced chicken	Unsubtyped
18	CDC NORS	1999	Chicken	chicken, unspecified	Unsubtyped
19	CDC NORS	2000	Chicken	chicken, unspecified	Group B
20	CDC NORS	2000	Chicken	chicken, bbq	Group C1
21	CDC NORS	2000	Chicken	chicken, fried	Newport
22	CDC NORS	2000	Chicken	chicken, unspecified	Newport
23	CDC NORS	2000	Chicken	chicken, unspecified	Typhimurium

24	CDC NORS	2001	Chicken	chicken, grilled	Braenderup
25	CDC NORS	2001	Chicken	chicken, nuggets/fingers	Enteritidis
26	CDC NORS	2001	Chicken	chicken, baked	Enteritidis
27	CDC NORS	2001	Chicken	chicken, fried	Newport
28	CDC NORS	2001	Chicken	specialty salads unspecified	Typhimurium
29	CDC NORS	2001	Chicken	chicken, other	Typhimurium
30	CDC NORS	2001	Chicken	chicken, other	Unsubtyped
31	CDC NORS	2001	Chicken	chicken, other	Unsubtyped
32	CDC NORS	2002	Chicken	chicken	Enteritidis
33	CDC NORS	2002	Chicken	chicken, other	Rubislaw
34	CDC NORS	2002	Chicken	chicken, baked	Unsubtyped
35	CDC NORS	2003	Chicken	sauces, unspecified; chicken, unspecified	Enteritidis
36	CDC NORS	2003	Chicken	chicken, baked	Enteritidis
37	CDC NORS	2003	Chicken	chicken, baked	Newport; Muenster; Heidelberg
38	CDC NORS	2003	Chicken	chicken, unspecified	Typhimurium
39	CDC NORS	2003	Chicken	chicken, other	Unsubtyped
40	CDC NORS	2003	Chicken	chicken, roasted	Unsubtyped
41	CDC NORS	2004	Chicken	chicken, raw	Enteritidis
42	CDC NORS	2004	Chicken	chicken, roasted	Group B
43	CDC NORS	2004	Chicken	chicken, curry	Group D1
44	CDC NORS	2004	Chicken	chicken, baked	Hadar
45	CDC NORS	2004	Chicken	chicken, other	Heidelberg
46	CDC NORS	2004	Chicken	chicken, unspecified	Heidelberg
47	CDC NORS	2004	Chicken	chicken, unspecified	Heidelberg
48	CDC NORS	2004	Chicken	chicken, other	Thompson
49	CDC NORS	2004	Chicken	chicken, baked	Typhimurium
50	CDC NORS	2004	Chicken	chicken, other	Typhimurium
51	CDC NORS	2004	Chicken	chicken, grilled	Typhimurium var Cope
52	CDC NORS	2004	Chicken	chicken, unspecified	Unsubtyped
53	CDC NORS	2005	Chicken	chicken, grilled	Enteritidis
54	CDC NORS	2005	Chicken	stuffing/dressing; gravy, chicken; chicken, other	Enteritidis
55	CDC NORS	2005	Chicken	chicken, grilled	Enteritidis
56	CDC NORS	2005	Chicken	stuffed chicken	Enteritidis; Typhimurium; Kentucky
57	CDC NORS	2005	Chicken	chicken, other	Heidelberg
58	CDC NORS	2005	Chicken	stuffed chicken (Chicken Broccoli and Cheese)	Heidelberg
59	CDC NORS	2005	Chicken	chicken, other	Unsubtyped
60	CDC NORS	2006	Chicken	chicken	Agona
61	CDC NORS	2006	Chicken	chicken, baked	I 4,[5],12:i:-
62	CDC NORS	2006	Chicken	chicken, unspecified	Newport
63	CDC NORS	2006	Chicken	chicken, teriyaki; sushi, unspecified	Typhimurium

64	PubMed	2006	Chicken	Chicken Kiev, Chicken Broccoli and Cheese, Chicken Mushrooms and Cheddar, Chicken Mushrooms in Wine Sauce, and/or Chicken Romanov	Typhimurium
65	CDC NORS	2006	Chicken	chicken, unspecified	Typhimurium var Cope
66	CDC NORS	2007	Chicken	chicken, bbq	Braenderup
67	CDC NORS	2007	Chicken	chicken dishes, unspecified	Enteritidis
68	CDC NORS	2007	Chicken	ribs, bbq; chicken wings, bbq	Enteritidis
69	CDC NORS	2007	Chicken	Not RTE frozen chicken pot pie	I 4,[5],12:i:-
70	CDC NORS	2007	Chicken	chicken	Schwarzengrund
71	CDC NORS	2007	Chicken	chicken, baked; chicken, grilled	Typhimurium
72	CDC NORS	2008	Chicken	specialty/ethnic dishes	Enteritidis
73	CDC NORS	2008	Chicken	chicken, roasted	Typhimurium
74	CDC NORS	2008	Chicken	chicken, other	Typhimurium
75	CDC NORS	2008	Chicken	chicken, unspecified	Typhimurium
76	CDC NORS	2009	Chicken	chicken	Heidelberg
77	CDC NORS	2009	Chicken	chicken	Heidelberg
78	FSIS/NORS	2009	Chicken	Stuffed chicken	1 4,[5], 12:i-
79	CDC NORS	2009	Chicken	chicken	Typhimurium
80	CDC NORS	2010	Chicken	Cheesy Chicken and Rice frozen meals (frozen entrée)	Chester
81	CDC NORS	2010	Chicken	chicken and rice	Enteritidis
82	CDC NORS	2010	Chicken	chicken salad	Enteritidis
83	CDC NORS	2010	Chicken	chicken	Heidelberg
84	CDC NORS	2010	Chicken	chicken, baked	Typhimurium var Cope
85	CDC NORS	2011	Chicken	chicken	Enteritidis
86	CDC NORS	2011	Chicken	chicken picata	Enteritidis
87	CDC NORS	2011	Chicken	chicken	Enteritidis
88	CDC NORS	2011	Chicken	Kosher Broiled Chicken Livers	Heidelberg
89	CDC NORS	2011	Chicken	chicken, other	Montevideo
90	CDC NORS	2011	Chicken	chicken	Typhimurium var Cope
91	CDC NORS	2012	Chicken	chicken	Enteritidis
92	CDC NORS	2012	Chicken	fajita, chicken	Enteritidis
93	CDC NORS	2012	Chicken	chicken	Heidelberg
94	CDC NORS	2012	Chicken	chicken, baked	Javiana
95	CDC NORS	2012	Chicken	chicken	Newport
96	CDC NORS	2012	Chicken	chicken	Schwarzengrund
97	CDC NORS	2012	Chicken	chicken	Unsubtyped
98	FSIS/NORS	2013	Chicken	Stuffed chicken	Enteritidis
99	CDC NORS	2013	Chicken	chicken	Enteritidis
100	CDC NORS	2013	Chicken	ground chicken	Enteritidis

101	CDC SNORS	2013	Chicken	Mechanically Separated Chicken	Heidelberg
102	CDC NORS	2013	Chicken	chicken	Heidelberg
103	CDC NORS	2013	Chicken	chicken mole	Heidelberg
104	CDC SNORS	2013	Chicken	chicken products	Heidelberg
105	CDC NORS	2013	Chicken	chicken	Javiana
106	CDC NORS	2013	Chicken	chicken, bbq	Montevideo
107	CDC NORS	2014	Chicken	chicken	Carmel
108	CDC NORS	2014	Chicken	chicken	Enteritidis
109	CDC NORS	2014	Chicken	chicken	Enteritidis
110	CDC NORS	2014	Chicken	chicken, casserole	Enteritidis
111	FSIS/NORS	2014	Chicken	stuffed chicken (chicken kiev)	Enteritidis
112	CDC NORS	2014	Chicken	chicken liver pate	Enteritidis
113	CDC NORS	2014	Chicken	chicken	Enteritidis; Enteritidis
114	CDC NORS	2014	Chicken	chicken, smoked	Heidelberg
115	CDC NORS	2014	Chicken	chicken, grilled	Heidelberg
116	CDC NORS	2014	Chicken	chicken	Infantis
117	CDC NORS	2014	Chicken	chicken, smoked	Thompson
118	CDC NORS	2014	Chicken	sandwich, chicken	Thompson
119	CDC NORS	2015	Chicken	chicken, rotisserie	Braenderup
120	CDC NORS	2015	Chicken	chicken, rotisserie	Derby
121	CDC NORS	2015	Chicken	Stuffed chicken	Enteritidis
122	CDC NORS	2015	Chicken	chicken tenders	Enteritidis
123	FSIS/NORS	2015	Chicken	frozen, raw, stuffed and breaded chicken	Enteritidis
124	FSIS/NORS	2015	Chicken	chicken Kiev, cordon bleu,	Enteritidis
125	CDC NORS	2015	Chicken	chicken, grilled; chicken, blackened	Enteritidis
126	CDC NORS	2015	Chicken	chicken and waffles	Enteritidis
127	CDC NORS	2015	Chicken	chicken katsu plate; korean chicken	Muenchen
128	CDC NORS	2015	Chicken	chicken, roasted	Unsubtyped
129	FSIS/NORS	2016	Chicken	Stuffed chicken	Enteritidis
130	CDC NORS	2016	Chicken	pate, chicken liver	Enteritidis
131	CDC NORS	2016	Chicken	chicken, baked	Enteritidis; Enteritidis; Enteritidis
132	CDC NORS	2016	Chicken	chicken	Heidelberg
133	CDC NORS	2016	Chicken	rotisserie chicken salad from Costco's Alderwood store	I 4,[5],12:i:-
134	CDC NORS	2016	Chicken	chicken	Muenchen;
135	CDC NORS	2016	Chicken	chicken	Norwich
136	CDC NORS	2016	Chicken	chicken	Saintpaul
137	CDC NORS	2016	Chicken	chicken	Thompson
138	CDC NORS	2016	Chicken	chicken	Unsubtyped
139	CDC NORS	2017	Chicken	sandwich, chicken	Anatum

140	CDC NORS	2017	Chicken	chicken	Enteritidis
141	CDC NORS	2017	Chicken	chicken	Enteritidis
142	CDC NORS	2017	Chicken	chicken dishes	Enteritidis
143	CDC NORS	2017	Chicken	kabobs, chicken	Enteritidis
144	CDC NORS	2017	Chicken	chicken salad sandwich; grilled chicken salad; chicken caesar salad	Enteritidis
145	CDC NORS	2017	Chicken	chicken	Enteritidis
146	CDC NORS	2017	Chicken	chicken	Enteritidis
147	CDC NORS	2017	Chicken	chicken, pulled	Heidelberg
148	CDC NORS	2017	Chicken	chicken	I 4,[5],12:i:-
149	CDC NORS	2017	Chicken	chicken, smoked	Infantis
150	CDC NORS	2018	Chicken	chicken, raw	Blockley
151	CDC NORS	2018	Chicken	chicken	Blockley
152	CDC NORS	2018	Chicken	chicken, grilled	Braenderup
153	CDC NORS	2018	Chicken	chicken	Enteritidis
154	FSIS/NORS	2018	Chicken	raw breaded chicken	Enteritidis
155	CDC NORS	2018	Chicken	chicken, smoked	Enteritidis
156	CDC NORS	2018	Chicken	smoked chicken	Enteritidis
157	CDC NORS	2018	Chicken	chicken, other	Enteritidis
158	CDC NORS	2018	Chicken	chicken	Enteritidis; Thompson
159	CDC NORS	2018	Chicken	chicken, raw	Heidelberg
160	CDC NORS	2018	Chicken	kosher chicken	I 4,[5],12:i:-
161	CDC NORS	2018	Chicken	chicken	Paratyphi B
162	CDC NORS	2018	Chicken	chicken salad	Typhimurium
163	CDC NORS	2018	Chicken	chicken	Typhimurium
164	CDC NORS	2019	Chicken	chicken	Braenderup
165	CDC NORS	2019	Chicken	chicken	Enteritidis
166	CDC NORS	2019	Chicken	chicken	Enteritidis
167	CDC NORS	2019	Chicken	chicken	Enteritidis
168	CDC NORS	2019	Chicken	chicken fingers	Enteritidis
169	CDC NORS	2019	Chicken	chicken	Enteritidis
170	CDC NORS	2019	Chicken	chicken	Enteritidis
171	CDC NORS	2019	Chicken	mechanically separated chicken	Enteritidis; Infantis
172	CDC NORS	2019	Chicken	chicken	Heidelberg
173	CDCNORS	2019	Chicken	chicken products	Infantis
174	CDC NORS	2019	Chicken	chicken	Infantis
175	CDC NORS	2019	Chicken	chicken	Thompson
176	CDC NORS	2020	Chicken	chicken	Enteritidis
177	CDC NORS	2020	Chicken	chicken	Enteritidis
178	CDC NORS	2020	Chicken	chicken	Enteritidis

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